US3252020 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:10:19

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Participant ID US3252020

mRNA-1273-P301 Completion Guidelines

US3252020
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 22:28:10**
Generated On: 11 Aug 2021 22:10:19

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	SCRN

US3252020

Folder: Screening

Form: Demographics

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	24
Age Units	YEARS
Age (Derived)	24
Sex	Female ◯
	Male ⬤
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ◯
	Not Reported ⬤
	Unknown ◯

Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	True

US3252020

Folder: Screening

Form: Enrollment

Data signed: (b) (4) **26 Feb 2021 22:28:10**

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Date of Informed Consent *(dd MMM yyyy)*	4 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version

- Amendment 1 ⬤
- Amendment 2 ◯
- Amendment 3 ◯
- Amendment 4 ◯
- Amendment 5 ◯

Was participant enrolled in the study?

- Yes ⬤
- No ◯

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

- Yes ◯
- No ⬤

If Yes, previous participant number _____

Enrollment Trigger	1

US3252020
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **26 Feb 2021 22:28:10**
Generated On: 11 Aug 2021 22:10:19

Did the participant meet all eligibility criteria?   Yes ⬤

                                                                                  No ◯

Were any significant conditions reported?　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

US3252020

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Feb 2021 22:28:10

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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening
Form: Vital Signs
Data signed: (b) (4) 26 Feb 2021 22:28:10
Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	4 AUG 2020
Time of assessment *(00:00-23:59)*	08:30 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 08:30
Height *(xxx.x)*	70.5 in
Weight *(xxx.x)*	190.2 lb
BMI *(xxx.x)*	26.96138 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) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

| Was the physical examination performed? | Yes ● |
| | No ○ |

| Date of examination *(dd MMM yyyy)* | 4 AUG 2020 |

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

US3252020
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) 26 Feb 2021 22:28:10
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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) **26 Feb 2021 22:28:10**

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

US3252020
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 22:28:10**
Generated On: 11 Aug 2021 22:10:19

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	4 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **26 Feb 2021 22:28:10**

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What was the date of randomization? *(dd MMM yyyy)*	04 AUG 2020
What was the participant's randomization number?	142802

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) **26 Feb 2021 22:28:10**

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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) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

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)*	04 AUG 2020
Time of assessment *(00:00-23:59)*	08:30 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 08:30
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 22:28:10

Generated On: 11 Aug 2021 22:10:19

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)*	04 AUG 2020
Time of assessment *(00:00-23:59)*	10:30 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 10:30
Temperature *(xxx.x)*	99.1 F
Route of measurement	Oral ⬤
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

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)* — 04 AUG 2020

What was the treatment time? *(00:00-23:59)* — 09:35 (24 HR)

Treatment Date and Time (derived) — 04 AUG 2020 09:35

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) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	4 AUG 2020
Collection time *(00:00-23:59)*	09:23 (24 HR)
Collection date and time (derived)	4 AUG 2020 09:23

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*			4 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:17	4 AUG 2020 09:17
Nasopharyngeal Swab 2	No		

US3252020
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 22:28:10**
Generated On: 11 Aug 2021 22:10:19

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**	

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	04 AUG 2020 09:55
PC Close Date & Time	04 AUG 2020 12:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	95.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	05 AUG 2020 02:27
PC Open Date & Time	04 AUG 2020 13:20
PC Close Date & Time	05 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 2

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.8 °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	06 AUG 2020 02:52
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:10:19

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	06 AUG 2020 22:12
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 4

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.3 °F

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

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

PC Time Stamp	07 AUG 2020 18:12
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯
Please record your **TEMPERATURE in °F**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

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

PC Time Stamp	09 AUG 2020 10:01
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 6

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

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

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

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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**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	09 AUG 2020 15:37
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.9 °F

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

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

PC Time Stamp	11 AUG 2020 01:49
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

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	04 AUG 2020 11:14
PC Open Date & Time	04 AUG 2020 09:55
PC Close Date & Time	04 AUG 2020 12:25

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

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	05 AUG 2020 02:25
PC Open Date & Time	04 AUG 2020 13:20
PC Close Date & Time	05 AUG 2020 11:59

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	05 AUG 2020 12:15
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:10:19

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	06 AUG 2020 19:39
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:19

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	07 AUG 2020 18:12
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:19

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	09 AUG 2020 09:49
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:19

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	09 AUG 2020 14:59
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:19

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	11 AUG 2020 01:48
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

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 ◯

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

PC Time stamp	
PC Open Date & Time	04 AUG 2020 09:55
PC Close Date & Time	04 AUG 2020 12:25

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19

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 ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ● Yes ◯
PC Time stamp	05 AUG 2020 02:27
PC Open Date & Time	04 AUG 2020 13:20
PC Close Date & Time	05 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19

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	05 AUG 2020 12:14
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 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	06 AUG 2020 19:39
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19

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 ●

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:19

	Yes ◯
PC Time stamp	07 AUG 2020 18:11
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:10:19

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	09 AUG 2020 09:49
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19

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 ●

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19

	Yes ◯
PC Time stamp	09 AUG 2020 14:59
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:19

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	11 AUG 2020 01:48
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3252020
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

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

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

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

Comments

If Contact Not Made, please provide Comments

US3252020

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?　　　　　　　　　Yes ⬤

No ⭘

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　1

US3252020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

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   _____

US3252020

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?	Yes ⬤
	No ◯

Continuing Flag   1

US3252020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

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

US3252020
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3252020
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 22:28:10**
Generated On: 11 Aug 2021 22:10:19

Was this visit performed?	Yes ⬤
	No ⭘

Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ⭘
	Clinic ⬤

Folder OID	VISIT2

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	4 SEP 2020
Time of assessment *(00:00-23:59)*	12:26 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 12:26
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 22:28:10

Generated On: 11 Aug 2021 22:10:19

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	

US3252020
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Feb 2021 22:28:10**
Generated On: 11 Aug 2021 22:10:19

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   AS PER PROTOCOL PATIENTS
Participant, Protocol Deviation, or Other, specify   THAT TEST POSITIVE FOR
                                                                 COVID CAN NO LONGER GET
                                                                 SECOND DOSE OF INJECTION.
                                                                 PATIENT AGREED TO STAY IN
                                                                 STUDY AND COMPLETE ALL
                                                                 RELEVANT PROCEDURES
                                                                 ALLOWED IN PROTOCOL.
                                                                 PATIENT AS

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?   _____

US3252020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

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

Collection date *(dd MMM yyyy)*	4 SEP 2020
Collection time *(00:00-23:59)*	12:25 (24 HR)
Collection date and time (derived)	4 SEP 2020 12:25

US3252020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*			4 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:05	4 SEP 2020 12:05
Nasopharyngeal Swab 2	No		

US3252020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3252020
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

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

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

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

Comments

If Contact Not Made, please provide Comments

US3252020
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

                                                                      No ○

Continuing Flag   1

US3252020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

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

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

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

Comments

If Contact Not Made, please provide Comments _____

US3252020

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3252020
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*   25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3252020

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?　　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3252020
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 22:28:10**
Generated On: 11 Aug 2021 22:10:19

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

| Visit date (dd MMM yyyy) | 30 SEP 2020 |

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

| Folder OID | VISIT3 |

US3252020
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Feb 2021 22:28:10**
Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	30 SEP 2020
Time of assessment *(00:00-23:59)*	11:09 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:09
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

Was the physical examination performed?
Yes ●
No ○

Date of examination *(dd MMM yyyy)*
30 SEP 2020

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

US3252020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	30 SEP 2020
Collection time *(00:00-23:59)*	11:26 (24 HR)
Collection date and time (derived)	30 SEP 2020 11:26

US3252020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 22:28:10**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	06 OCT 2020 16:28:15
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	14 OCT 2020 08:50:23
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	19 OCT 2020 15:25:30
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	05 NOV 2020 09:01:48
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	11 NOV 2020 08:31:53
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	16 NOV 2020 23:21:55
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 12:52:23
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 00:26:19
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 18:03:03
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ⃝

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ●
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 18:03:56
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ●
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ●
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 01:55:33
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	11 JAN 2021 12:34:50
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 166**

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

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

Fever (Temperature ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	29 JAN 2021 13:04:06
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	04 FEB 2021 10:04:20
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	11 FEB 2021 10:04:27
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 10:03:04
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	01 MAR 2021 13:52:43
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	08 MAR 2021 14:40:16
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT   DAY 229

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 236**

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

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

Fever (Temperature ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	02 APR 2021 12:59:01
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	08 APR 2021 10:23:45
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

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	15 APR 2021 00:19:33
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	23 APR 2021 14:56:47
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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	30 APR 2021 17:10:18
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 278**

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

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

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 ⭘

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 285**

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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 ⚪

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 306**

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

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

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 ⚪

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT DAY 334

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

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

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

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

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

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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 ⃝

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 362

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

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

Fever (Temperature ≥ 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 ⬭

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 376**

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ⃝

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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-2022-1614-0708980

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 418**

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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-2022-1614-0708994

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ○

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 502**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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-2022-1614-0709010

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT DAY 523

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

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):

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 537**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

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

FDA-CBER-2022-1614-0709016

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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 ○

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 551

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

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

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

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

FDA-CBER-2022-1614-0709020

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT <div align="right">**DAY 558**</div>

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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 ⃝

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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-2022-1614-0709026

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	03 MAR 2022 00:01
Patient Cloud Close Date & Time	07 MAR 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ⟳

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 593**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

FDA-CBER-2022-1614-0709032

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	24 MAR 2022 00:01
Patient Cloud Close Date & Time	28 MAR 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 607**

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 MAR 2022 00:01
Patient Cloud Close Date & Time	04 APR 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ○

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

FDA-CBER-2022-1614-0709044

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ⬭

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ⬭

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	19 MAY 2022 00:01
Patient Cloud Close Date & Time	23 MAY 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 670

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

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

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

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

FDA-CBER-2022-1614-0709054

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 677

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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-2022-1614-0709058

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	**DAY 691**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

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

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ⃝

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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-2022-1614-0709064

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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-2022-1614-0709068

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT DAY 726

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

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

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

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

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	28 JUL 2022 00:01
Patient Cloud Close Date & Time	01 AUG 2022 23:59

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):

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT	DAY 740

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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):

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-2022-1614-0709076

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	18 AUG 2022 00:01
Patient Cloud Close Date & Time	22 AUG 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

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

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

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ≥ 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 ⭘

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

FDA-CBER-2022-1614-0709086

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ⊙

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3252020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:10:19

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		01 MAR 2021 13:52:55

US3252020
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

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

Date of Contact or Contact Attempt *(dd MMM yyyy)* — 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3252020
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3252020
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 DEC 2020
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●

| Comments | LEFT VOICE MAIL |

If Contact Not Made, please provide Comments

US3252020

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?　　　　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3252020
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 JAN 2021
Please select one status for the follow-up contact	Contact Made ○
	Contact Not Made ●
Comments	LEFT VOICE MAIL

If Contact Not Made, please provide Comments

US3252020

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

                                                          No ○

Continuing Flag   1

US3252020
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

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   _____

US3252020

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) 05 Mar 2021 20:07:46
Generated On: 11 Aug 2021 22:10:19

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT4

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) 05 Apr 2021 19:37:51
Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	3 MAR 2021
Time of assessment *(00:00-23:59)*	11:32 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 11:32
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0709102

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.

US3252020
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 20:07:46**
Generated On: 11 Aug 2021 22:10:19

Was the sample collected?   Yes ◯

                                                                No ⬤

Collection date *(dd MMM yyyy)* _____

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

Collection date and time (derived) _____

US3252020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3252020
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **04 May 2021 00:27:08**
Generated On: 11 Aug 2021 22:10:19

| 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 _____

US3252020

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **04 May 2021 00:27:08**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

                                                          No ○

Continuing Flag   1

US3252020

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) **04 May 2021 00:27:08**

Generated On: 11 Aug 2021 22:10:19

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*   30 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3252020

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) **04 May 2021 00:27:08**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?
Yes ●
No ○

Continuing Flag 1

US3252020
Folder: Safety Call Day 299 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

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 _____

US3252020
Folder: Safety Call Day 299 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ◯

                                                                                                        No ◯

Continuing Flag _____

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID-19 Contact
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

Date of Contact	17 AUG 2020
Time of Contact	17:00
Date and Time of Contact (derived)	17 AUG 2020 17:00
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	13 AUG 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
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 ⬭

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done

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 ◯

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	98 %
O2 Saturation Units	%
Temperature	99.1 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 ◯

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	18 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.9 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 ⬭

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	
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	98.6 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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	20 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97 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 ⭕

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

	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 ○

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

	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	99 %
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 ⭕

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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 ◯

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Data signed: (b) (4) 26 Feb 2021 22:28:07
Generated On: 11 Aug 2021 22:10:19

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-2022-1614-0709149

	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	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 ◯

FDA-CBER-2022-1614-0709150

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 ⚪

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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 ○

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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	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 ⚪

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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-2022-1614-0709156

US3252020

Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Data signed: (b) (4) 26 Feb 2021 22:28:07
Generated On: 11 Aug 2021 22:10:19

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	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 ◯

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Data signed: (b) (4) 26 Feb 2021 22:28:07
Generated On: 11 Aug 2021 22:10:19

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	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 ◯

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

	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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Data signed: (b) (4) 26 Feb 2021 22:28:07
Generated On: 11 Aug 2021 22:10:19

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	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 ◯

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

	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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	27 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.6 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-2022-1614-0709170

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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 ○

US3252020

Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Data signed: (b) (4) 26 Feb 2021 22:28:07
Generated On: 11 Aug 2021 22:10:19

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	97.5 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 ◯

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

	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 ○

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	96 %
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 ◯

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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 ⭘

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

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	True
O2 Saturation	
O2 Saturation Units	
Temperature	
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 ◯

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Data signed: (b) (4) 26 Feb 2021 22:28:07
Generated On: 11 Aug 2021 22:10:19

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	◯

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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

Date	31 AUG 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
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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EAB) (1725)

	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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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

Date of Visit	17 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	17 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

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

Did the subject have Respiratory Rates ≥ 30 per Minute?   Yes ◯
                                                            No ●

If Yes, provide:

  Start Date _____

  End Date _____

  Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute   Yes ◯
                                                            No ●

If Yes, provide:

  Start Date _____

  End Date _____

  Heart Rate _____

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air   Yes ◯
at sea level?   No ●

If Yes, provide:

  Start Date _____

  End Date _____

  Oxygen Saturation _____

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 _____

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?	Yes ◯
	No ⬤
Start Date	
End Date	
Non-Invasive Ventilation?	Yes ◯
	No ⬤
Start Date	
End Date	
Mechanical Ventilation?	Yes ◯
	No ⬤
Start Date	
End Date	
ECMO?	Yes ◯
	No ⬤
Start Date	
End Date	

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ◯
	No ⬤
Start Date	
End Date	
Evidence of Shock Requires Vasopressors	Yes ◯
	No ⬤
Start Date	
End Date	
Acute Renal Dysfunction?	Yes ◯
	No ⬤
Start Date	

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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 _____

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **26 Feb 2021 22:28:07**
Generated On: 11 Aug 2021 22:10:19

Generate Next COVID-19 Assessment

Yes ◯
No ⬤

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **28 Apr 2021 11:32:22**

Generated On: 11 Aug 2021 22:10:19

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	19 AUG 2020
Day 5	Yes	21 AUG 2020
Day 7	Yes	23 AUG 2020
Day 9	Yes	25 AUG 2020
Day 14	Yes	30 AUG 2020
Day 21	Yes	06 SEP 2020
Day 28	No	

US3252020
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 22:28:08**
Generated On: 11 Aug 2021 22:10:19

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SICKD1

US3252020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) **26 Feb 2021 22:28:08**

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	17 AUG 2020
Time of assessment *(00:00-23:59)*	15:00 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:00
Height *(xxx.x)*	70.5 in
Weight *(xxx.x)*	190 lb
Temperature *(xxx.x)*	99.1 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252020
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Feb 2021 22:28:08**
Generated On: 11 Aug 2021 22:10:19

Was the physical examination performed?   Yes ●

                                                                           No ◯

Date of examination *(dd MMM yyyy)*   17 AUG 2020

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

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) **26 Feb 2021 22:28:08**

Generated On: 11 Aug 2021 22:10:19

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

Date of Collection	17 AUG 2020

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US3252020

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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   SICKD28

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) 26 Feb 2021 22:28:07
Generated On: 11 Aug 2021 22:10:19

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)	_____

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US3252020

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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.

US3252020

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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

Date of Collection

US3252020

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

Form: Visit Date

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3252020

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 19:37:50

Generated On: 11 Aug 2021 22:10:19

Date of updated informed consent *(dd MMM yyyy)*	3 MAR 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)*	3 MAR 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	1
Continuing with mRNA-1273	1

US3252020

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

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

US3252020

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

Height	ND - Not Done
Weight	
BMI *(xxx.x)*	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	3 MAR 2021
Time of assessment *(00:00-23:59)*	11:32 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 11:32
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3252020

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

Height	ND - Not Done
Weight	
BMI *(xxx.x)*	
Timepoint	Pre-Dose ⭕
	Post-Dose ⚫
Were vital signs assessed?	Yes ⚫
	No ⭕
Date of assessment *(dd MMM yyyy)*	3 MAR 2021
Time of assessment *(00:00-23:59)*	12:30 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 12:30
Temperature *(xxx.x)*	99.2 F
Route of measurement	Oral ⚫
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	62 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)*	75 mmHg
Diastolic Blood Pressure units	MMHG

US3252020

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

Form: Physical Examination

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	3 MAR 2021
What was the treatment time? *(00:00-23:59)*	11:58 (24 HR)
Treatment Date and Time (derived)	3 MAR 2021 11:58

Which arm was used to give treatment?   Left Arm ●

                                                        Right Arm ○

What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) 05 Mar 2021 20:07:46
Generated On: 11 Aug 2021 22:10:19

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	3 MAR 2021
Collection time *(00:00-23:59)*	11:48 (24 HR)
Collection date and time (derived)	3 MAR 2021 11:48

US3252020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	3 MAR 2021
Collection time *(00:00 - 23:59)*	11:48
Collection Date and Time (derived)	3 MAR 2021 11:48

US3252020

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

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:07:46**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3252020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **05 Apr 2021 19:37:51**

Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?	Yes ●
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 MAR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3252020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 19:37:51**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?	Yes ●
	No ○

Continuing Flag	1
OLD29 Placebo Flag	1

US3252020
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **05 Apr 2021 19:37:50**
Generated On: 11 Aug 2021 22:10:19

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD29

US3252020
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **05 Apr 2021 19:37:50**
Generated On: 11 Aug 2021 22:10:19

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	31 MAR 2021
Time of assessment *(00:00-23:59)*	09:23 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 09:23
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3252020
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) 05 Apr 2021 19:37:50
Generated On: 11 Aug 2021 22:10:19

Timepoint	Pre-Dose ⃝
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⃝
Date of assessment *(dd MMM yyyy)*	31 MAR 2021
Time of assessment *(00:00-23:59)*	10:59 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 10:59
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ⬤
	Axillary ⃝
	Other ⃝
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 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? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	31 MAR 2021
What was the treatment time? *(00:00-23:59)*	10:30 (24 HR)
Treatment Date and Time (derived)	31 MAR 2021 10:30
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

US3252020

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 19:37:49**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3252020
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **22 Apr 2021 18:43:37**
Generated On: 11 Aug 2021 22:10:19

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*   7 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3252020

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **22 Apr 2021 18:43:37**

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?   Yes ⬤

                                                                                      No ◯

Continuing Flag   1

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

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) _____

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.

US3252020

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?	Yes ◯
	No ◯

Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

US3252020

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

Did the participant experience any adverse events?   Yes ●

                                                                     No ○

If Yes, enter details on the Adverse Events form.

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **22 Apr 2021 18:43:36**

Generated On: 11 Aug 2021 22:10:19

AEID	USA-US108-2020-MRNA-1273-P30 1000002
Adverse event	COVID-19 INFECTION

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

Was this a Solicited Adverse Reaction? Yes ○ / No ●

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

Start date *(dd MMM yyyy)*	13 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ / No ●

If not Ongoing, end date *(dd MMM yyyy)*	30 AUG 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 ○

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **22 Apr 2021 18:43:36**

Generated On: 11 Aug 2021 22:10:19

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	SYMPTOMATIC PATIENT HAD A COVID NASOPHARYNGEAL SWAB FOR RT-PCR ANALYSIS. RESULTS CAME BACK AS "DETECTED".
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003 EAB) (1725)

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FDA-CBER-2022-1614-0709229

Admitted to ICU Derived (CSA Programming Field Only)

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

Name of Medication	AZITHROMYCIN

Prophylaxis	Yes ⚪
	No ⬤

Indication	COVID +
Dose per administration	250

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

If dose unit is Other, specify	_____

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

If frequency is Other, specify	_____

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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)*	17 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	22 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 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

Name of Medication	BROMFED DM
Prophylaxis	Yes ◯
	No ⬤

Indication	COVID +
Dose per administration	10

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 ◯

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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)*	17 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	31 AUG 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

Name of Medication	ASPIRIN

Prophylaxis	Yes ⚪
	No ⬤

Indication	COVID +
Dose per administration	325

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 ⚪

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

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)*	17 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	22 AUG 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3252020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **26 Feb 2021 22:28:07**

Generated On: 11 Aug 2021 22:10:19

Were any concomitant procedures performed?   Yes ◯

                                                         No ⬤

If yes, please complete Concomitant Procedures form.

Date of dosing discontinuation (dd MMM yyyy)	29 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	◯

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

SAEID	USA-US108-2020-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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3252020

Folder: SAE USA-US108-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

SAEID	USA-US108-2020-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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/OCT/2020 13:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252020

Folder: SAE USA-US108-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

SAEID	USA-US108-2020-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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:36
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

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form (3)
Data signed: (b) (4) **26 Feb 2021 22:28:09**
Generated On: 11 Aug 2021 22:10:19

SAEID	USA-US108-2020-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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/OCT/2020 20:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252020

Folder: SAE USA-US108-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) **26 Feb 2021 22:28:09**

Generated On: 11 Aug 2021 22:10:19

SAEID	USA-US108-2020-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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/NOV/2020 08:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3252020 (Prod: Centex Studies Inc)

US3252020

Form: Participant Creation

Generated On: 11 Aug 2021 22:10:19

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'US3252020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:24:58

US3252020
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:14:36

US3252020
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:24:59

US3252020
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:14:36

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'SCRN'	System	05 Aug 2020 07:14:36

US3252020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered (b) (6) 1996'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:25:00

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '24'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'YEARS'	System	05 Aug 2020 07:15:04

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered '24'	System	04 Aug 2020 15:13:00

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Male (M)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Not Reported (NOT REPORTED)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:19

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney	05 Aug 2020 07:15:04
	(b) (4)	

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:19

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney	05 Aug 2020 07:15:04
	(b) (4)	

US3252020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:19

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney	05 Aug 2020 07:15:04
	(b) (4)	

US3252020
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:10:19
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:10:19

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '1'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:04

US3252020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:19

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:00

US3252020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:19

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'Aug 2020'	System	04 Aug 2020 15:13:00

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3252020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:19

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered '2020'	System	04 Aug 2020 15:13:00

US3252020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:19

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 07:15:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 07:15:19
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:19
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 15:13:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:00

US3252020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:19

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:00

US3252020
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:10:19
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:00

US3252020
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:10:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:00

US3252020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:19

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 07:15:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 07:15:19
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:19
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 15:13:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:00

US3252020
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:10:19
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:24:59

US3252020

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:10:19

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered '1'	System	04 Aug 2020 15:13:06

US3252020

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:10:19

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:06

US3252020

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:10:19

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:37

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 07:17:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 07:17:08
Data point term sent to Coder	System	05 Aug 2020 07:16:20
User entered 'Depression'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'un UNK 2008'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'Jan 2008'	System	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered '2008'	System	05 Aug 2020 07:15:57

US3252020
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:10:19
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered empty.	System	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:10:19

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered empty.	System	05 Aug 2020 07:15:57

US3252020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '08:30'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered '4 Aug 2020 08:30'	System	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '70.5' in	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16
DataPoint set to visible.	System	04 Aug 2020 15:13:06

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '190.2' lb	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16
DataPoint set to visible.	System	04 Aug 2020 15:13:06

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
Amendment Manager: User entered '26.96138'	System	16 Sep 2020 23:42:07
User entered '27.0'	System	05 Aug 2020 07:17:16
DataPoint set to visible.	System	04 Aug 2020 15:13:06

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'kg/m2'	System	05 Aug 2020 07:17:16
DataPoint set to visible.	System	04 Aug 2020 15:13:06

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 06:19:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:49:40
User entered '97.9' F	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 02:12:48
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:49:49
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 02:49:40
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:49:40
User entered 'Oral (Oral)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:49:40
User entered '62'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'bpm'	System	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:49:40
User entered '16'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'breaths/min'	System	05 Aug 2020 07:17:16

US3252020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:49:40
User entered '129'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'mmHg'	System	05 Aug 2020 07:17:16

US3252020

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:49:40
User entered '78'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User entered 'mmHg'	System	05 Aug 2020 07:17:16

US3252020
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	05 Aug 2020 07:17:33
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 12:19:50
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	05 Sep 2020 16:30:34
User entered '4 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:17:33

US3252020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney	05 Aug 2020 07:18:28
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:10:19
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:10:19
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney	05 Aug 2020 07:18:28
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '0'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:10:19
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '1'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:10:19
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:56:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Resident in a community with ongoing person to person transmission'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:28

US3252020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:54

US3252020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:54

US3252020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:18:54

US3252020

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'VISIT1'	System	05 Aug 2020 07:18:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:14:42

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US3252020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:19

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:53:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:53:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 14:14:42
User entered '142802' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:14:42

US3252020
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:10:19

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:26:05
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'participant was stratified incorrectly, unable to correct' (Site from System).	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:12:54
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:11:09
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:11:09
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	05 Aug 2020 07:20:05
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 14:14:42

US3252020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:19

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:20:05

US3252020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:19

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:20:05

US3252020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:20:05

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney	05 Aug 2020 07:20:05
	(b) (4)	

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US3252020

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:10:19

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:20:05

US3252020
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:10:19
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 21:26:12
User entered empty.	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:10:19
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 21:26:12
User entered empty.	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:10:19
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 21:26:12
User entered empty.	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 21:26:12
User entered empty.	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:10:19
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '04 Aug 2020'	Shannon Moyer (b) (4)	19 Aug 2020 02:51:34
	(b) (4)	

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '08:30'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '04 Aug 2020 08:30'	System	19 Aug 2020 02:51:34

FDA-CBER-2022-1614-0709353

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '97.9' F	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '62'	Shannon Moyer (b) (4)	19 Aug 2020 02:51:34
	(b) (4)	

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'bpm'	System	19 Aug 2020 02:51:34

FDA-CBER-2022-1614-0709358

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '16'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'breaths/min'	System	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '129'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'mmHg'	System	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '78'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'mmHg'	System	19 Aug 2020 02:51:34

US3252020
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:10:19
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 21:26:12
User entered empty.	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	21 Aug 2020 21:26:12
User entered empty.	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '04 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
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)	20 Aug 2020 12:34:40
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per Source, correct as is' (Site from System).	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:51
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	19 Aug 2020 02:51:34
User entered '10:30'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '04 Aug 2020 10:30'	System	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '99.1' F	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '59'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

US3252020
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'bpm'	System	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '16'	Shannon Moyer (b) (4) (b) (4)	19 Aug 2020 02:51:34

FDA-CBER-2022-1614-0709377

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'breaths/min'	System	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '123'	Shannon Moyer (b) (4)	19 Aug 2020 02:51:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'mmHg'	System	19 Aug 2020 02:51:34

US3252020

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '79'	Shannon Moyer (b) (4)	19 Aug 2020 02:51:34
	(b) (4)	

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'mmHg'	System	19 Aug 2020 02:51:34

FDA-CBER-2022-1614-0709382

US3252020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 06:20:43
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:20:18

US3252020

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 06:20:43
User entered '4 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:20:18

US3252020
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:10:19

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:28

US3252020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:28

US3252020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:28

US3252020
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:10:19
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 15:13:28

US3252020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:46:32
Query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' answered with 'Date format updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 21:55:48
User entered '04 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 21:55:22
User opened query ' Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:11:56
User entered '4 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:28

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '09:35'	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:28

US3252020

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '04 Aug 2020 09:35'	System	06 Nov 2020 21:55:22
User entered '4 Aug 2020 09:35'	System	04 Aug 2020 15:13:28

US3252020
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:10:19
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney (b) (4)	04 Aug 2020 15:13:28

US3252020
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:10:19
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'ONCE'	System	04 Aug 2020 15:13:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 15:13:28

US3252020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:21:13

US3252020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:21:13

US3252020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '09:23' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	06 Aug 2020 02:55:11
User entered '09:17'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:21:13

US3252020

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '4 Aug 2020 09:23'	System	06 Aug 2020 02:55:11
User entered '4 Aug 2020 09:17'	System	05 Aug 2020 07:21:13

US3252020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:19

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:35

US3252020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:35

US3252020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '09:17'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '4 Aug 2020 09:17'	System	05 Aug 2020 07:22:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:35

US3252020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:35

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:35

US3252020

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	05 Aug 2020 07:22:35

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:44

US3252020
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '1'	System	05 Aug 2020 07:22:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 09:55'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 12:25'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:25:18', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b9b2ac22-3c78-47f2-8aa3-defdf005c36f'	System	05 Aug 2020 07:27:16
User entered 'Yes (Y)'	System	05 Aug 2020 07:27:16

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:25:25', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b9b2ac22-3c78-47f2-8aa3-defdf005c36f'	System	05 Aug 2020 07:27:16
User entered '95.0'	System	05 Aug 2020 07:27:16

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:08', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b9b2ac22-3c78-47f2-8aa3-defdf005c36f'	System	05 Aug 2020 07:27:16
User entered 'No (N)'	System	05 Aug 2020 07:27:16

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:12', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b9b2ac22-3c78-47f2-8aa3-defdf005c36f'	System	05 Aug 2020 07:27:16
User entered '05 Aug 2020 02:27'	System	05 Aug 2020 07:27:16

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 13:20'	System	04 Aug 2020 15:13:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 2'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T02:51:42', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'dec5f35d-16e9-4b00-af3e-9c8d565e954a'	System	06 Aug 2020 07:52:32
User entered 'Yes (Y)'	System	06 Aug 2020 07:52:32

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T02:52:20', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'dec5f35d-16e9-4b00-af3e-9c8d565e954a'	System	06 Aug 2020 07:52:32
User entered '97.8'	System	06 Aug 2020 07:52:32

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T02:52:27', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'dec5f35d-16e9-4b00-af3e-9c8d565e954a'	System	06 Aug 2020 07:52:32
User entered 'No (N)'	System	06 Aug 2020 07:52:32

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T02:52:30', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'dec5f35d-16e9-4b00-af3e-9c8d565e954a'	System	06 Aug 2020 07:52:32
User entered '06 Aug 2020 02:52'	System	06 Aug 2020 07:52:32

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

FDA-CBER-2022-1614-0709432

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 3'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:10:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T22:12:03', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '723790db-ed80-413b-ac1e-e04ec24c7b36'	System	07 Aug 2020 03:12:18
User entered 'Yes (Y)'	System	07 Aug 2020 03:12:18

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T22:12:08', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '723790db-ed80-413b-ac1e-e04ec24c7b36'	System	07 Aug 2020 03:12:18
User entered '97.6'	System	07 Aug 2020 03:12:18

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T22:12:11', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '723790db-ed80-413b-ac1e-e04ec24c7b36'	System	07 Aug 2020 03:12:18
User entered 'No (N)'	System	07 Aug 2020 03:12:18

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:19

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T22:12:13', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '723790db-ed80-413b-ac1e-e04ec24c7b36'	System	07 Aug 2020 03:12:18
User entered '06 Aug 2020 22:12'	System	07 Aug 2020 03:12:18

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:10:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 4'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:12:25', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '5a84d21b-7d56-44f0-a579-51a346df19d7'	System	07 Aug 2020 23:12:40
User entered 'Yes (Y)'	System	07 Aug 2020 23:12:40

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:12:32', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '5a84d21b-7d56-44f0-a579-51a346df19d7'	System	07 Aug 2020 23:12:40
User entered '98.3'	System	07 Aug 2020 23:12:40

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:12:35', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '5a84d21b-7d56-44f0-a579-51a346df19d7'	System	07 Aug 2020 23:12:40
User entered 'No (N)'	System	07 Aug 2020 23:12:40

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:10:19

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:12:37', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '5a84d21b-7d56-44f0-a579-51a346df19d7'	System	07 Aug 2020 23:12:40
User entered '07 Aug 2020 18:12'	System	07 Aug 2020 23:12:40

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

FDA-CBER-2022-1614-0709446

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 5'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T10:01:02', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3de89fd2-be2f-4b3d-b498-60a84d10c645'	System	09 Aug 2020 15:01:20
User entered 'Yes (Y)'	System	09 Aug 2020 15:01:20

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:10:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T10:01:07', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3de89fd2-be2f-4b3d-b498-60a84d10c645'	System	09 Aug 2020 15:01:20
User entered '97.3'	System	09 Aug 2020 15:01:20

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T10:01:09', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3de89fd2-be2f-4b3d-b498-60a84d10c645'	System	09 Aug 2020 15:01:20
User entered 'No (N)'	System	09 Aug 2020 15:01:20

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:19

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T10:01:14', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3de89fd2-be2f-4b3d-b498-60a84d10c645'	System	09 Aug 2020 15:01:20
User entered '09 Aug 2020 10:01'	System	09 Aug 2020 15:01:20

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:10:19

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 6'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T15:37:24', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e7594b37-e80a-4dd0-8d34-f045470f3377'	System	09 Aug 2020 20:37:37
User entered 'Yes (Y)'	System	09 Aug 2020 20:37:37

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T15:37:28', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e7594b37-e80a-4dd0-8d34-f045470f3377'	System	09 Aug 2020 20:37:37
User entered '98.5'	System	09 Aug 2020 20:37:37

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T15:37:32', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e7594b37-e80a-4dd0-8d34-f045470f3377'	System	09 Aug 2020 20:37:37
User entered 'No (N)'	System	09 Aug 2020 20:37:37

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T15:37:35', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e7594b37-e80a-4dd0-8d34-f045470f3377'	System	09 Aug 2020 20:37:37
User entered '09 Aug 2020 15:37'	System	09 Aug 2020 20:37:37

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:10:19

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 7'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:59', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3b6db14c-20df-4da5-b409-5de509da9f0c'	System	11 Aug 2020 06:49:11
User entered 'Yes (Y)'	System	11 Aug 2020 06:49:11

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:49:03', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3b6db14c-20df-4da5-b409-5de509da9f0c'	System	11 Aug 2020 06:49:11
User entered '97.9'	System	11 Aug 2020 06:49:11

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:49:05', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3b6db14c-20df-4da5-b409-5de509da9f0c'	System	11 Aug 2020 06:49:11
User entered 'No (N)'	System	11 Aug 2020 06:49:11

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:49:07', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3b6db14c-20df-4da5-b409-5de509da9f0c'	System	11 Aug 2020 06:49:11
User entered '11 Aug 2020 01:49'	System	11 Aug 2020 06:49:11

US3252020

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:10:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-04T11:13:37', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '1d4bebfc-5e99-4f09-830c-27025aba992b'	System	04 Aug 2020 16:14:17
User entered 'None (1)'	System	04 Aug 2020 16:14:17

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-04T11:14:02', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '1d4bebfc-5e99-4f09-830c-27025aba992b'	System	04 Aug 2020 16:14:17
User entered 'No (N)'	System	04 Aug 2020 16:14:17

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-04T11:14:06', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '1d4bebfc-5e99-4f09-830c-27025aba992b'	System	04 Aug 2020 16:14:17
User entered 'No (N)'	System	04 Aug 2020 16:14:17

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-04T11:14:12', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '1d4bebfc-5e99-4f09-830c-27025aba992b'	System	04 Aug 2020 16:14:17
User entered 'None (1)'	System	04 Aug 2020 16:14:17

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-04T11:14:16', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '1d4bebfc-5e99-4f09-830c-27025aba992b'	System	04 Aug 2020 16:14:17
User entered '04 Aug 2020 11:14'	System	04 Aug 2020 16:14:17

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 09:55'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 12:25'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:24:53', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'faa5aa76-7ad9-41b7-98cb-6718a24e2f41'	System	05 Aug 2020 07:25:15
User entered 'None (1)'	System	05 Aug 2020 07:25:15

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:25:02', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'faa5aa76-7ad9-41b7-98cb-6718a24e2f41'	System	05 Aug 2020 07:25:15
User entered 'No (N)'	System	05 Aug 2020 07:25:15

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:25:04', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'faa5aa76-7ad9-41b7-98cb-6718a24e2f41'	System	05 Aug 2020 07:25:15
User entered 'No (N)'	System	05 Aug 2020 07:25:15

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:25:07', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'faa5aa76-7ad9-41b7-98cb-6718a24e2f41'	System	05 Aug 2020 07:25:15
User entered 'None (1)'	System	05 Aug 2020 07:25:15

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:25:10', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'faa5aa76-7ad9-41b7-98cb-6718a24e2f41'	System	05 Aug 2020 07:25:15
User entered '05 Aug 2020 02:25'	System	05 Aug 2020 07:25:15

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 13:20'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 2'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:15:09', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '55950b38-bd8e-4588-9ff2-2dece9a207f9'	System	05 Aug 2020 17:15:27
User entered 'None (1)'	System	05 Aug 2020 17:15:27

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:15:12', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '55950b38-bd8e-4588-9ff2-2dece9a207f9'	System	05 Aug 2020 17:15:27
User entered 'No (N)'	System	05 Aug 2020 17:15:27

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:10:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:15:15', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '55950b38-bd8e-4588-9ff2-2dece9a207f9'	System	05 Aug 2020 17:15:27
User entered 'No (N)'	System	05 Aug 2020 17:15:27

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:15:21', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '55950b38-bd8e-4588-9ff2-2dece9a207f9'	System	05 Aug 2020 17:15:27
User entered 'None (1)'	System	05 Aug 2020 17:15:27

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:10:19

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:15:23', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '55950b38-bd8e-4588-9ff2-2dece9a207f9'	System	05 Aug 2020 17:15:27
User entered '05 Aug 2020 12:15'	System	05 Aug 2020 17:15:27

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 3'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:19

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:39:11', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9c9ea694-f0a1-4db8-ade7-5ef2e5377049'	System	07 Aug 2020 00:39:46
User entered 'None (1)'	System	07 Aug 2020 00:39:46

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:39:24', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9c9ea694-f0a1-4db8-ade7-5ef2e5377049'	System	07 Aug 2020 00:39:46
User entered 'No (N)'	System	07 Aug 2020 00:39:46

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:39:33', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9c9ea694-f0a1-4db8-ade7-5ef2e5377049'	System	07 Aug 2020 00:39:46
User entered 'No (N)'	System	07 Aug 2020 00:39:46

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:10:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:39:38', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9c9ea694-f0a1-4db8-ade7-5ef2e5377049'	System	07 Aug 2020 00:39:46
User entered 'None (1)'	System	07 Aug 2020 00:39:46

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:39:43', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9c9ea694-f0a1-4db8-ade7-5ef2e5377049'	System	07 Aug 2020 00:39:46
User entered '06 Aug 2020 19:39'	System	07 Aug 2020 00:39:46

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 4'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:11:59', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0102ade9-0a39-4ca2-8f9e-8d13333cc9db'	System	07 Aug 2020 23:12:18
User entered 'None (1)'	System	07 Aug 2020 23:12:18

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:12:08', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0102ade9-0a39-4ca2-8f9e-8d13333cc9db'	System	07 Aug 2020 23:12:18
User entered 'No (N)'	System	07 Aug 2020 23:12:18

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:12:10', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0102ade9-0a39-4ca2-8f9e-8d13333cc9db'	System	07 Aug 2020 23:12:18
User entered 'No (N)'	System	07 Aug 2020 23:12:18

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:19

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:12:13', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0102ade9-0a39-4ca2-8f9e-8d13333cc9db'	System	07 Aug 2020 23:12:18
User entered 'None (1)'	System	07 Aug 2020 23:12:18

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:10:19

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:12:15', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0102ade9-0a39-4ca2-8f9e-8d13333cc9db'	System	07 Aug 2020 23:12:18
User entered '07 Aug 2020 18:12'	System	07 Aug 2020 23:12:18

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 5'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:41', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '861edbe0-8dcd-43b3-9f97-9577f32ebd7f'	System	09 Aug 2020 14:49:59
User entered 'None (1)'	System	09 Aug 2020 14:49:59

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:49', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '861edbe0-8dcd-43b3-9f97-9577f32ebd7f'	System	09 Aug 2020 14:49:59
User entered 'No (N)'	System	09 Aug 2020 14:49:59

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:51', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '861edbe0-8dcd-43b3-9f97-9577f32ebd7f'	System	09 Aug 2020 14:49:59
User entered 'No (N)'	System	09 Aug 2020 14:49:59

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:53', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '861edbe0-8dcd-43b3-9f97-9577f32ebd7f'	System	09 Aug 2020 14:49:59
User entered 'None (1)'	System	09 Aug 2020 14:49:59

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:10:19

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:56', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '861edbe0-8dcd-43b3-9f97-9577f32ebd7f'	System	09 Aug 2020 14:49:59
User entered '09 Aug 2020 09:49'	System	09 Aug 2020 14:49:59

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 6'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:59:11', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'cd5cbc3d-30de-4fe6-87d8-3bdd00b9fa31'	System	09 Aug 2020 19:59:21
User entered 'None (1)'	System	09 Aug 2020 19:59:21

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:59:13', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'cd5cbc3d-30de-4fe6-87d8-3bdd00b9fa31'	System	09 Aug 2020 19:59:21
User entered 'No (N)'	System	09 Aug 2020 19:59:21

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:59:15', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'cd5cbc3d-30de-4fe6-87d8-3bdd00b9fa31'	System	09 Aug 2020 19:59:21
User entered 'No (N)'	System	09 Aug 2020 19:59:21

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:59:17', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'cd5cbc3d-30de-4fe6-87d8-3bdd00b9fa31'	System	09 Aug 2020 19:59:21
User entered 'None (1)'	System	09 Aug 2020 19:59:21

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:59:19', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'cd5cbc3d-30de-4fe6-87d8-3bdd00b9fa31'	System	09 Aug 2020 19:59:21
User entered '09 Aug 2020 14:59'	System	09 Aug 2020 19:59:21

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:10:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 7'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:42', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b3f61b4f-89f9-4cfa-8bac-de90f820d9b7'	System	11 Aug 2020 06:48:55
User entered 'None (1)'	System	11 Aug 2020 06:48:55

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:45', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b3f61b4f-89f9-4cfa-8bac-de90f820d9b7'	System	11 Aug 2020 06:48:55
User entered 'No (N)'	System	11 Aug 2020 06:48:55

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:10:19
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:47', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b3f61b4f-89f9-4cfa-8bac-de90f820d9b7'	System	11 Aug 2020 06:48:55
User entered 'No (N)'	System	11 Aug 2020 06:48:55

US3252020

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:10:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:49', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b3f61b4f-89f9-4cfa-8bac-de90f820d9b7'	System	11 Aug 2020 06:48:55
User entered 'None (1)'	System	11 Aug 2020 06:48:55

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:10:19
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:51', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b3f61b4f-89f9-4cfa-8bac-de90f820d9b7'	System	11 Aug 2020 06:48:55
User entered '11 Aug 2020 01:48'	System	11 Aug 2020 06:48:55

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:10:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 09:55'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:10:19

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 12:25'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:37', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8bec61aa-c176-4a72-a54f-ca29dbde45a5'	System	05 Aug 2020 07:28:01
User entered 'None (0)'	System	05 Aug 2020 07:28:01

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:40', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8bec61aa-c176-4a72-a54f-ca29dbde45a5'	System	05 Aug 2020 07:28:01
User entered 'None (0)'	System	05 Aug 2020 07:28:01

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:42', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8bec61aa-c176-4a72-a54f-ca29dbde45a5'	System	05 Aug 2020 07:28:01
User entered 'None (0)'	System	05 Aug 2020 07:28:01

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:45', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8bec61aa-c176-4a72-a54f-ca29dbde45a5'	System	05 Aug 2020 07:28:01
User entered 'None (0)'	System	05 Aug 2020 07:28:01

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:47', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8bec61aa-c176-4a72-a54f-ca29dbde45a5'	System	05 Aug 2020 07:28:01
User entered 'None (0)'	System	05 Aug 2020 07:28:01

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:50', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8bec61aa-c176-4a72-a54f-ca29dbde45a5'	System	05 Aug 2020 07:28:01
User entered 'None (0)'	System	05 Aug 2020 07:28:01

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:57', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8bec61aa-c176-4a72-a54f-ca29dbde45a5'	System	05 Aug 2020 07:28:01
User entered 'No (N)'	System	05 Aug 2020 07:28:01

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T02:27:59', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8bec61aa-c176-4a72-a54f-ca29dbde45a5'	System	05 Aug 2020 07:28:01
User entered '05 Aug 2020 02:27'	System	05 Aug 2020 07:28:01

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '04 Aug 2020 13:20'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:10:19

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 2'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:14:37', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b34f3499-4215-4c82-b59a-a316a4eaf6c6'	System	05 Aug 2020 17:15:02
User entered 'None (0)'	System	05 Aug 2020 17:15:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:14:40', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b34f3499-4215-4c82-b59a-a316a4eaf6c6'	System	05 Aug 2020 17:15:02
User entered 'None (0)'	System	05 Aug 2020 17:15:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:14:42', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b34f3499-4215-4c82-b59a-a316a4eaf6c6'	System	05 Aug 2020 17:15:02
User entered 'None (0)'	System	05 Aug 2020 17:15:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:14:44', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b34f3499-4215-4c82-b59a-a316a4eaf6c6'	System	05 Aug 2020 17:15:02
User entered 'None (0)'	System	05 Aug 2020 17:15:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:14:46', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b34f3499-4215-4c82-b59a-a316a4eaf6c6'	System	05 Aug 2020 17:15:02
User entered 'None (0)'	System	05 Aug 2020 17:15:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:14:47', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b34f3499-4215-4c82-b59a-a316a4eaf6c6'	System	05 Aug 2020 17:15:02
User entered 'None (0)'	System	05 Aug 2020 17:15:02

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:14:53', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b34f3499-4215-4c82-b59a-a316a4eaf6c6'	System	05 Aug 2020 17:15:02
User entered 'No (N)'	System	05 Aug 2020 17:15:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-05T12:14:55', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b34f3499-4215-4c82-b59a-a316a4eaf6c6'	System	05 Aug 2020 17:15:02
User entered '05 Aug 2020 12:14'	System	05 Aug 2020 17:15:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 3'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:10:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:38:43', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0f19a40b-ca41-494b-a4ee-c5d2457366b5'	System	07 Aug 2020 00:39:02
User entered 'None (0)'	System	07 Aug 2020 00:39:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:10:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:38:45', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0f19a40b-ca41-494b-a4ee-c5d2457366b5'	System	07 Aug 2020 00:39:02
User entered 'None (0)'	System	07 Aug 2020 00:39:02

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:38:50', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0f19a40b-ca41-494b-a4ee-c5d2457366b5'	System	07 Aug 2020 00:39:02
User entered 'None (0)'	System	07 Aug 2020 00:39:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:10:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:38:52', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0f19a40b-ca41-494b-a4ee-c5d2457366b5'	System	07 Aug 2020 00:39:02
User entered 'None (0)'	System	07 Aug 2020 00:39:02

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:10:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:38:54', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0f19a40b-ca41-494b-a4ee-c5d2457366b5'	System	07 Aug 2020 00:39:02
User entered 'None (0)'	System	07 Aug 2020 00:39:02

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:38:55', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0f19a40b-ca41-494b-a4ee-c5d2457366b5'	System	07 Aug 2020 00:39:02
User entered 'None (0)'	System	07 Aug 2020 00:39:02

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:38:58', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0f19a40b-ca41-494b-a4ee-c5d2457366b5'	System	07 Aug 2020 00:39:02
User entered 'No (N)'	System	07 Aug 2020 00:39:02

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:19

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-06T19:39:01', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '0f19a40b-ca41-494b-a4ee-c5d2457366b5'	System	07 Aug 2020 00:39:02
User entered '06 Aug 2020 19:39'	System	07 Aug 2020 00:39:02

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:10:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 4'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:10:35', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '65342494-e3f0-489e-b4d4-0b0d523a878b'	System	07 Aug 2020 23:11:11
User entered 'None (0)'	System	07 Aug 2020 23:11:11

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:10:37', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '65342494-e3f0-489e-b4d4-0b0d523a878b'	System	07 Aug 2020 23:11:11
User entered 'None (0)'	System	07 Aug 2020 23:11:11

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:10:39', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '65342494-e3f0-489e-b4d4-0b0d523a878b'	System	07 Aug 2020 23:11:11
User entered 'None (0)'	System	07 Aug 2020 23:11:11

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:10:42', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '65342494-e3f0-489e-b4d4-0b0d523a878b'	System	07 Aug 2020 23:11:11
User entered 'None (0)'	System	07 Aug 2020 23:11:11

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:10:44', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '65342494-e3f0-489e-b4d4-0b0d523a878b'	System	07 Aug 2020 23:11:11
User entered 'None (0)'	System	07 Aug 2020 23:11:11

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:10:46', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '65342494-e3f0-489e-b4d4-0b0d523a878b'	System	07 Aug 2020 23:11:11
User entered 'None (0)'	System	07 Aug 2020 23:11:11

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:11:04', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '65342494-e3f0-489e-b4d4-0b0d523a878b'	System	07 Aug 2020 23:11:11
User entered 'No (N)'	System	07 Aug 2020 23:11:11

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:19

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-07T18:11:08', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '65342494-e3f0-489e-b4d4-0b0d523a878b'	System	07 Aug 2020 23:11:11
User entered '07 Aug 2020 18:11'	System	07 Aug 2020 23:11:11

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:10:19

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 5'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:10:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:22', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'bb088eee-e964-4064-b315-670840d6384e'	System	09 Aug 2020 14:49:40
User entered 'None (0)'	System	09 Aug 2020 14:49:40

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:10:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:23', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'bb088eee-e964-4064-b315-670840d6384e'	System	09 Aug 2020 14:49:40
User entered 'None (0)'	System	09 Aug 2020 14:49:40

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:10:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:25', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'bb088eee-e964-4064-b315-670840d6384e'	System	09 Aug 2020 14:49:40
User entered 'None (0)'	System	09 Aug 2020 14:49:40

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:10:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:27', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'bb088eee-e964-4064-b315-670840d6384e'	System	09 Aug 2020 14:49:40
User entered 'None (0)'	System	09 Aug 2020 14:49:40

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:10:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:28', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'bb088eee-e964-4064-b315-670840d6384e'	System	09 Aug 2020 14:49:40
User entered 'None (0)'	System	09 Aug 2020 14:49:40

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:30', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'bb088eee-e964-4064-b315-670840d6384e'	System	09 Aug 2020 14:49:40
User entered 'None (0)'	System	09 Aug 2020 14:49:40

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:32', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'bb088eee-e964-4064-b315-670840d6384e'	System	09 Aug 2020 14:49:40
User entered 'No (N)'	System	09 Aug 2020 14:49:40

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:19

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T09:49:34', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'bb088eee-e964-4064-b315-670840d6384e'	System	09 Aug 2020 14:49:40
User entered '09 Aug 2020 09:49'	System	09 Aug 2020 14:49:40

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:10:19

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 6'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:58:49', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '4a6f31b9-e2e9-4262-8bcf-29490bbba47c'	System	09 Aug 2020 19:59:08
User entered 'None (0)'	System	09 Aug 2020 19:59:08

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:58:51', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '4a6f31b9-e2e9-4262-8bcf-29490bbba47c'	System	09 Aug 2020 19:59:08
User entered 'None (0)'	System	09 Aug 2020 19:59:08

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:58:53', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '4a6f31b9-e2e9-4262-8bcf-29490bbba47c'	System	09 Aug 2020 19:59:08
User entered 'None (0)'	System	09 Aug 2020 19:59:08

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:58:54', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '4a6f31b9-e2e9-4262-8bcf-29490bbba47c'	System	09 Aug 2020 19:59:08
User entered 'None (0)'	System	09 Aug 2020 19:59:08

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:58:56', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '4a6f31b9-e2e9-4262-8bcf-29490bbba47c'	System	09 Aug 2020 19:59:08
User entered 'None (0)'	System	09 Aug 2020 19:59:08

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:58:58', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '4a6f31b9-e2e9-4262-8bcf-29490bbba47c'	System	09 Aug 2020 19:59:08
User entered 'None (0)'	System	09 Aug 2020 19:59:08

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:59:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '4a6f31b9-e2e9-4262-8bcf-29490bbba47c'	System	09 Aug 2020 19:59:08
User entered 'No (N)'	System	09 Aug 2020 19:59:08

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:10:19

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-09T14:59:02', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '4a6f31b9-e2e9-4262-8bcf-29490bbba47c'	System	09 Aug 2020 19:59:08
User entered '09 Aug 2020 14:59'	System	09 Aug 2020 19:59:08

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 7'	System	04 Aug 2020 15:13:28

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:10:19
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:47:56', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd97df5ca-fca2-4a79-839e-91fe027df4e7'	System	11 Aug 2020 06:48:39
User entered 'None (0)'	System	11 Aug 2020 06:48:39

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:10:19
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:47:59', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd97df5ca-fca2-4a79-839e-91fe027df4e7'	System	11 Aug 2020 06:48:39
User entered 'None (0)'	System	11 Aug 2020 06:48:39

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:10:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:01', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd97df5ca-fca2-4a79-839e-91fe027df4e7'	System	11 Aug 2020 06:48:39
User entered 'None (0)'	System	11 Aug 2020 06:48:39

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:10:19
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:03', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd97df5ca-fca2-4a79-839e-91fe027df4e7'	System	11 Aug 2020 06:48:39
User entered 'None (0)'	System	11 Aug 2020 06:48:39

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:10:19
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:21', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd97df5ca-fca2-4a79-839e-91fe027df4e7'	System	11 Aug 2020 06:48:39
User entered 'None (0)'	System	11 Aug 2020 06:48:39

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:10:19
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:24', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd97df5ca-fca2-4a79-839e-91fe027df4e7'	System	11 Aug 2020 06:48:39
User entered 'None (0)'	System	11 Aug 2020 06:48:39

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:30', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd97df5ca-fca2-4a79-839e-91fe027df4e7'	System	11 Aug 2020 06:48:39
User entered 'No (N)'	System	11 Aug 2020 06:48:39

US3252020

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:10:19

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-08-11T01:48:33', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd97df5ca-fca2-4a79-839e-91fe027df4e7'	System	11 Aug 2020 06:48:39
User entered '11 Aug 2020 01:48'	System	11 Aug 2020 06:48:39

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:10:19
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 15:13:28

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EAB) (1725)

US3252020
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:10:19
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 21:28:11

US3252020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '13 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 21:28:11

US3252020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 21:28:11

US3252020

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 21:28:11

US3252020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	13 Aug 2020 21:28:51

US3252020

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User entered '1'	System	13 Aug 2020 21:28:51

US3252020
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:16:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 16:16:32
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	25 Sep 2020 16:16:32
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:16:26
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	25 Sep 2020 16:16:26
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 21:14:11

US3252020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	25 Sep 2020 16:16:26
User entered '19 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 21:14:11

US3252020

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	25 Sep 2020 16:16:26
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 21:14:11

US3252020
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 21:14:11

US3252020
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 21:14:18

US3252020
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User entered '1'	System	23 Aug 2020 21:14:18

US3252020
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	05 Sep 2020 16:28:07

US3252020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	05 Sep 2020 16:28:07

US3252020

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	05 Sep 2020 16:28:07

US3252020
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4)	05 Sep 2020 16:28:07
	(b) (4)	

US3252020

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	05 Sep 2020 16:28:17

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User entered '1'	System	05 Sep 2020 16:28:17

FDA-CBER-2022-1614-0709637

US3252020
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	05 Sep 2020 16:30:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	05 Sep 2020 16:30:34

US3252020

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	05 Sep 2020 16:30:34

US3252020
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'VISIT2'	System	05 Sep 2020 16:30:34

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Sep 2020'	Shannon Moyer (b) (4)	08 Sep 2020 16:41:53
	(b) (4)	

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '12:26'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '4 Sep 2020 12:26'	System	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '97.6' F	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:10:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '70'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:10:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'bpm'	System	08 Sep 2020 16:41:53

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '15'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'breaths/min'	System	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis　(b) (4)	26 Feb 2021 22:28:11
User entered '124'	Shannon Moyer (b) (4)　(b) (4)	08 Sep 2020 16:41:53

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'mmHg'	System	08 Sep 2020 16:41:53

FDA-CBER-2022-1614-0709655

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '83'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'mmHg'	System	08 Sep 2020 16:41:53

US3252020
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 16:41:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 16:41:57
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:57
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 16:41:53
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4)	08 Sep 2020 16:41:53
	(b) (4)	

US3252020
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:41:53

US3252020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:05

US3252020

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:05

US3252020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:44:54

US3252020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Confirmed COVID-19 (COVID)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:44:54

US3252020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'As per protocol patients that test positive for COVID can no longer get second dose of injection. Patient agreed to stay in study and complete all relevant procedures allowed in protocol. Patient as'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:44:54

US3252020
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:10:19
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:44:54

US3252020
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4)	08 Sep 2020 16:44:54
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:44:54

US3252020
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:10:19
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:44:54

US3252020
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:10:19
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:44:54

US3252020

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:44:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:44:54

US3252020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis　(b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:30

US3252020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:30

US3252020

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '12:25'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '4 Sep 2020 12:25'	System	08 Sep 2020 16:40:30

US3252020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:48

US3252020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:19

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:48

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:48

US3252020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '12:05'	Shannon Moyer (b) (4)	08 Sep 2020 16:40:48
	(b) (4)	

US3252020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:10:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '4 Sep 2020 12:05'	System	08 Sep 2020 16:40:48

US3252020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:19

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:48

US3252020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:48

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:40:48

US3252020

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:10:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered empty.	System	08 Sep 2020 16:40:48

US3252020

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 16:45:14

US3252020
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '1'	System	08 Sep 2020 16:45:14

US3252020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	10 Sep 2020 05:10:48
	(b) (4)	

US3252020

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '9 Sep 2020'	Shannon Moyer (b) (4)	10 Sep 2020 05:10:48
	(b) (4)	

US3252020
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 05:10:48

US3252020
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 05:10:48

US3252020

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 05:10:54

US3252020
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User entered '1'	System	10 Sep 2020 05:10:54

US3252020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	19 Sep 2020 04:41:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '18 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	19 Sep 2020 04:41:59

US3252020

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	19 Sep 2020 04:41:59

US3252020
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Nancy Torrence (b) (4)	19 Sep 2020 04:41:59
	(b) (4)	

US3252020
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	19 Sep 2020 04:42:03

US3252020
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User entered '1'	System	19 Sep 2020 04:42:03

US3252020
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	26 Sep 2020 05:54:57

US3252020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '25 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	26 Sep 2020 05:54:57

US3252020

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	26 Sep 2020 05:54:57

US3252020
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Nancy Torrence (b) (4) (b) (4)	26 Sep 2020 05:54:57

US3252020

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	26 Sep 2020 05:55:02

US3252020
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User entered '1'	System	26 Sep 2020 05:55:02

US3252020
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:36:49

US3252020
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 20:36:49

US3252020

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Oct 2020 20:36:49

US3252020
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'VISIT3'	System	01 Oct 2020 20:36:49

US3252020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:37:20

US3252020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 20:37:20

US3252020
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '11:09'	(b) (4), (b) (6)	01 Oct 2020 20:37:20

US3252020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '30 Sep 2020 11:09'	System	01 Oct 2020 20:37:20

US3252020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '98.3' F	(b) (4), (b) (6)	01 Oct 2020 20:37:20

US3252020
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 20:37:20

US3252020
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:37:20

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '69'	(b) (4), (b) (6)	01 Oct 2020 20:37:20

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'bpm'	System	01 Oct 2020 20:37:20

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '15'	(b) (4), (b) (6)	01 Oct 2020 20:37:20

FDA-CBER-2022-1614-0709732

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'breaths/min'	System	01 Oct 2020 20:37:20

FDA-CBER-2022-1614-0709733

US3252020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '120'	(b) (4), (b) (6)	01 Oct 2020 20:37:20

US3252020
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'mmHg'	System	01 Oct 2020 20:37:20

US3252020

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '70'	(b) (4), (b) (6)	01 Oct 2020 20:37:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered 'mmHg'	System	01 Oct 2020 20:37:20

FDA-CBER-2022-1614-0709737

US3252020
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:37:43

US3252020

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 20:37:43

US3252020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis　(b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:38:00

US3252020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 20:38:00

US3252020

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '11:26'	(b) (4), (b) (6)	01 Oct 2020 20:38:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '30 Sep 2020 11:26'	System	01 Oct 2020 20:38:00

US3252020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:38:09

US3252020

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 00:06:57
User entered '1'	System	01 Oct 2020 20:38:09

US3252020
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 64'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-06T16:28:04', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '237eec73-fdc5-4728-992e-4e4d752da50e'	System	06 Oct 2020 21:28:22
User entered 'No (N)'	System	06 Oct 2020 21:28:22

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-06T16:28:12', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '237eec73-fdc5-4728-992e-4e4d752da50e'	System	06 Oct 2020 21:28:22
User entered 'No (N)'	System	06 Oct 2020 21:28:22

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-06T16:28:15', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '237eec73-fdc5-4728-992e-4e4d752da50e'	System	06 Oct 2020 21:28:22
User entered '06 Oct 2020 16:28:15'	System	06 Oct 2020 21:28:22

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 71'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-14T08:50:17', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8f6db8c7-3e12-4610-8a33-9c4ebf13c4e8'	System	14 Oct 2020 13:50:25
User entered 'No (N)'	System	14 Oct 2020 13:50:25

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-14T08:50:20', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8f6db8c7-3e12-4610-8a33-9c4ebf13c4e8'	System	14 Oct 2020 13:50:25
User entered 'No (N)'	System	14 Oct 2020 13:50:25

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-14T08:50:23', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '8f6db8c7-3e12-4610-8a33-9c4ebf13c4e8'	System	14 Oct 2020 13:50:25
User entered '14 Oct 2020 08:50:23'	System	14 Oct 2020 13:50:25

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 78'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-19T15:25:20', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3c5c1ae0-1308-44b3-ba84-c65eaa5bb77d'	System	19 Oct 2020 20:25:33
User entered 'No (N)'	System	19 Oct 2020 20:25:33

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-19T15:25:27', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3c5c1ae0-1308-44b3-ba84-c65eaa5bb77d'	System	19 Oct 2020 20:25:33
User entered 'No (N)'	System	19 Oct 2020 20:25:33

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-10-19T15:25:30', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3c5c1ae0-1308-44b3-ba84-c65eaa5bb77d'	System	19 Oct 2020 20:25:33
User entered '19 Oct 2020 15:25:30'	System	19 Oct 2020 20:25:33

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 15:13:28

US3252020
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 92'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-05T09:01:41', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '66611a55-14a7-4c86-8a00-8afe3f5067e4'	System	05 Nov 2020 15:01:51
User entered 'No (N)'	System	05 Nov 2020 15:01:51

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-05T09:01:44', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '66611a55-14a7-4c86-8a00-8afe3f5067e4'	System	05 Nov 2020 15:01:51
User entered 'No (N)'	System	05 Nov 2020 15:01:51

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-05T09:01:48', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '66611a55-14a7-4c86-8a00-8afe3f5067e4'	System	05 Nov 2020 15:01:51
User entered '05 Nov 2020 09:01:48'	System	05 Nov 2020 15:01:51

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 99'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-11T08:31:44', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'def749a7-730f-4613-8398-7d76f8570106'	System	11 Nov 2020 14:31:57
User entered 'No (N)'	System	11 Nov 2020 14:31:57

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-11T08:31:49', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'def749a7-730f-4613-8398-7d76f8570106'	System	11 Nov 2020 14:31:57
User entered 'No (N)'	System	11 Nov 2020 14:31:57

US3252020
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-11T08:31:53', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'def749a7-730f-4613-8398-7d76f8570106'	System	11 Nov 2020 14:31:57
User entered '11 Nov 2020 08:31:53'	System	11 Nov 2020 14:31:57

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 15:13:28

US3252020
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered 'Day 106'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-16T23:21:37', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd6d0be97-107e-4414-9cd4-e6d6f377bfff'	System	17 Nov 2020 05:21:58
User entered 'No (N)'	System	17 Nov 2020 05:21:58

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-16T23:21:53', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd6d0be97-107e-4414-9cd4-e6d6f377bfff'	System	17 Nov 2020 05:21:58
User entered 'No (N)'	System	17 Nov 2020 05:21:58

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-16T23:21:55', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd6d0be97-107e-4414-9cd4-e6d6f377bfff'	System	17 Nov 2020 05:21:58
User entered '16 Nov 2020 23:21:55'	System	17 Nov 2020 05:21:58

US3252020
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 15:13:28

US3252020

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:35:55
Data entry locked.	System	04 Aug 2020 15:13:28
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 15:13:28

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2020-11-20T12:52:18', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'f3e68999-b0e4-414b-bafa-b012a895ff9b'	System	20 Nov 2020 18:52:27
User entered 'No (N)'	System	20 Nov 2020 18:52:27

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2020-11-20T12:52:21', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'f3e68999-b0e4-414b-bafa-b012a895ff9b'	System	20 Nov 2020 18:52:27
User entered 'No (N)'	System	20 Nov 2020 18:52:27

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-11-20T12:52:23', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'f3e68999-b0e4-414b-bafa-b012a895ff9b'	System	20 Nov 2020 18:52:27
User entered '20 Nov 2020 12:52:23'	System	20 Nov 2020 18:52:27

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2020-12-03T00:26:13', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '5ddc8b00-fab9-4076-b801-f15923bc81b1'	System	03 Dec 2020 06:26:22
User entered 'No (N)'	System	03 Dec 2020 06:26:22

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2020-12-03T00:26:17', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '5ddc8b00-fab9-4076-b801-f15923bc81b1'	System	03 Dec 2020 06:26:22
User entered 'No (N)'	System	03 Dec 2020 06:26:22

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-12-03T00:26:19', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '5ddc8b00-fab9-4076-b801-f15923bc81b1'	System	03 Dec 2020 06:26:22
User entered '03 Dec 2020 00:26:19'	System	03 Dec 2020 06:26:22

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2020-12-11T18:02:58', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '2bfe4209-9405-44f9-86ff-a034ea8ed91c'	System	12 Dec 2020 00:03:11
User entered 'No (N)'	System	12 Dec 2020 00:03:11

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2020-12-11T18:03:01', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '2bfe4209-9405-44f9-86ff-a034ea8ed91c'	System	12 Dec 2020 00:03:11
User entered 'No (N)'	System	12 Dec 2020 00:03:11

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-12-11T18:03:03', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '2bfe4209-9405-44f9-86ff-a034ea8ed91c'	System	12 Dec 2020 00:03:11
User entered '11 Dec 2020 18:03:03'	System	12 Dec 2020 00:03:11

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2020-12-25T18:03:29', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b7e07a3c-cd6b-44f0-beaa-7870c177e1d0'	System	26 Dec 2020 00:04:09
User entered 'No (N)'	System	26 Dec 2020 00:04:09

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2020-12-25T18:03:32', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b7e07a3c-cd6b-44f0-beaa-7870c177e1d0'	System	26 Dec 2020 00:04:09
User entered 'Yes (Y)'	System	26 Dec 2020 00:04:09

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please 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 (ffb3c6f8085e76a6)', Time: '2020-12-25T18:03:48', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b7e07a3c-cd6b-44f0-beaa-7870c177e1d0'	System	26 Dec 2020 00:04:09
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Dec 2020 00:04:09

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-12-25T18:03:56', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b7e07a3c-cd6b-44f0-beaa-7870c177e1d0'	System	26 Dec 2020 00:04:09
User entered '25 Dec 2020 18:03:56'	System	26 Dec 2020 00:04:09

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2020-12-31T01:55:20', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9ed8219d-8b92-47c5-9f8c-6f23d048c96f'	System	31 Dec 2020 07:55:44
User entered 'No (N)'	System	31 Dec 2020 07:55:44

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2020-12-31T01:55:28', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9ed8219d-8b92-47c5-9f8c-6f23d048c96f'	System	31 Dec 2020 07:55:44
User entered 'Yes (Y)'	System	31 Dec 2020 07:55:44

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Please 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 (ffb3c6f8085e76a6)', Time: '2020-12-31T01:55:30', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9ed8219d-8b92-47c5-9f8c-6f23d048c96f'	System	31 Dec 2020 07:55:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Dec 2020 07:55:44

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2020-12-31T01:55:33', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9ed8219d-8b92-47c5-9f8c-6f23d048c96f'	System	31 Dec 2020 07:55:44
User entered '31 Dec 2020 01:55:33'	System	31 Dec 2020 07:55:44

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-01-11T12:34:45', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b9438c91-3cf7-4006-8448-efbdc7509d12'	System	11 Jan 2021 18:34:54
User entered 'No (N)'	System	11 Jan 2021 18:34:54

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-01-11T12:34:48', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b9438c91-3cf7-4006-8448-efbdc7509d12'	System	11 Jan 2021 18:34:54
User entered 'No (N)'	System	11 Jan 2021 18:34:54

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-01-11T12:34:50', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'b9438c91-3cf7-4006-8448-efbdc7509d12'	System	11 Jan 2021 18:34:54
User entered '11 Jan 2021 12:34:50'	System	11 Jan 2021 18:34:54

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:19:47

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-01-29T13:04:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '63f23b1c-7355-4a56-ac5f-1e21639b0670'	System	29 Jan 2021 19:04:08
User entered 'No (N)'	System	29 Jan 2021 19:04:08

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-01-29T13:04:03', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '63f23b1c-7355-4a56-ac5f-1e21639b0670'	System	29 Jan 2021 19:04:08
User entered 'No (N)'	System	29 Jan 2021 19:04:08

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-01-29T13:04:06', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '63f23b1c-7355-4a56-ac5f-1e21639b0670'	System	29 Jan 2021 19:04:08
User entered '29 Jan 2021 13:04:06'	System	29 Jan 2021 19:04:08

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-02-04T10:04:13', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '002dbb7f-2e71-481c-9fcb-fef26113562a'	System	04 Feb 2021 16:04:25
User entered 'No (N)'	System	04 Feb 2021 16:04:25

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-02-04T10:04:17', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '002dbb7f-2e71-481c-9fcb-fef26113562a'	System	04 Feb 2021 16:04:25
User entered 'No (N)'	System	04 Feb 2021 16:04:25

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-02-04T10:04:20', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '002dbb7f-2e71-481c-9fcb-fef26113562a'	System	04 Feb 2021 16:04:25
User entered '04 Feb 2021 10:04:20'	System	04 Feb 2021 16:04:25

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-02-11T10:04:23', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '6fbd1289-880b-4e06-a075-d2ed66ce9019'	System	11 Feb 2021 16:04:31
User entered 'No (N)'	System	11 Feb 2021 16:04:31

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-02-11T10:04:25', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '6fbd1289-880b-4e06-a075-d2ed66ce9019'	System	11 Feb 2021 16:04:31
User entered 'No (N)'	System	11 Feb 2021 16:04:31

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-02-11T10:04:27', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '6fbd1289-880b-4e06-a075-d2ed66ce9019'	System	11 Feb 2021 16:04:31
User entered '11 Feb 2021 10:04:27'	System	11 Feb 2021 16:04:31

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:19:47

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-02-18T10:03:01', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '97695692-f5ba-4e0a-a9df-230d4d13be22'	System	18 Feb 2021 16:03:09
User entered 'No (N)'	System	18 Feb 2021 16:03:09

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-02-18T10:03:03', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '97695692-f5ba-4e0a-a9df-230d4d13be22'	System	18 Feb 2021 16:03:09
User entered 'No (N)'	System	18 Feb 2021 16:03:09

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-02-18T10:03:04', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '97695692-f5ba-4e0a-a9df-230d4d13be22'	System	18 Feb 2021 16:03:09
User entered '18 Feb 2021 10:03:04'	System	18 Feb 2021 16:03:09

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-03-01T13:52:38-06:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9ad55ffa-4c27-42d0-9653-2da50e8c320f'	System	01 Mar 2021 19:52:48
User entered 'No (N)'	System	01 Mar 2021 19:52:48

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-03-01T13:52:42-06:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9ad55ffa-4c27-42d0-9653-2da50e8c320f'	System	01 Mar 2021 19:52:48
User entered 'No (N)'	System	01 Mar 2021 19:52:48

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-03-01T13:52:43-06:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '9ad55ffa-4c27-42d0-9653-2da50e8c320f'	System	01 Mar 2021 19:52:48
User entered '01 Mar 2021 13:52:43'	System	01 Mar 2021 19:52:48

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-03-08T14:40:10-06:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd300b1d3-3289-4ef2-8456-2a9ecaefa873'	System	08 Mar 2021 20:40:20
User entered 'No (N)'	System	08 Mar 2021 20:40:20

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-03-08T14:40:13-06:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd300b1d3-3289-4ef2-8456-2a9ecaefa873'	System	08 Mar 2021 20:40:20
User entered 'No (N)'	System	08 Mar 2021 20:40:20

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-03-08T14:40:16-06:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'd300b1d3-3289-4ef2-8456-2a9ecaefa873'	System	08 Mar 2021 20:40:20
User entered '08 Mar 2021 14:40:16'	System	08 Mar 2021 20:40:20

FDA-CBER-2022-1614-0709867

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:19:47

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-03-15T11:30:11-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'cc3317a8-95e6-46b0-877a-59d053311c3a'	System	15 Mar 2021 16:30:21
User entered 'No (N)'	System	15 Mar 2021 16:30:21

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-03-15T11:30:12-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'cc3317a8-95e6-46b0-877a-59d053311c3a'	System	15 Mar 2021 16:30:21
User entered 'No (N)'	System	15 Mar 2021 16:30:21

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-03-15T11:30:15-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'cc3317a8-95e6-46b0-877a-59d053311c3a'	System	15 Mar 2021 16:30:21
User entered '15 Mar 2021 11:30:15'	System	15 Mar 2021 16:30:21

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:19:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0709876

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-04-02T12:58:57-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '87fa5f4d-726e-4342-b30d-c8110a6e092a'	System	02 Apr 2021 17:59:03
User entered 'No (N)'	System	02 Apr 2021 17:59:03

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-04-02T12:58:59-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '87fa5f4d-726e-4342-b30d-c8110a6e092a'	System	02 Apr 2021 17:59:03
User entered 'No (N)'	System	02 Apr 2021 17:59:03

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-04-02T12:59:01-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '87fa5f4d-726e-4342-b30d-c8110a6e092a'	System	02 Apr 2021 17:59:03
User entered '02 Apr 2021 12:59:01'	System	02 Apr 2021 17:59:03

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0709888

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-04-08T10:23:39-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'f87e74a2-c51d-480b-9238-762a507402aa'	System	08 Apr 2021 15:23:50
User entered 'No (N)'	System	08 Apr 2021 15:23:50

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-04-08T10:23:43-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'f87e74a2-c51d-480b-9238-762a507402aa'	System	08 Apr 2021 15:23:50
User entered 'No (N)'	System	08 Apr 2021 15:23:50

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-04-08T10:23:45-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'f87e74a2-c51d-480b-9238-762a507402aa'	System	08 Apr 2021 15:23:50
User entered '08 Apr 2021 10:23:45'	System	08 Apr 2021 15:23:50

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-04-15T00:19:29-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3049ad01-6406-436f-9d5d-f4ec7b0f6126'	System	15 Apr 2021 05:19:37
User entered 'No (N)'	System	15 Apr 2021 05:19:37

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-04-15T00:19:31-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3049ad01-6406-436f-9d5d-f4ec7b0f6126'	System	15 Apr 2021 05:19:37
User entered 'No (N)'	System	15 Apr 2021 05:19:37

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-04-15T00:19:33-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '3049ad01-6406-436f-9d5d-f4ec7b0f6126'	System	15 Apr 2021 05:19:37
User entered '15 Apr 2021 00:19:33'	System	15 Apr 2021 05:19:37

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-04-23T14:56:44-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '00831343-07e4-437f-b42a-34a358d3142f'	System	23 Apr 2021 19:56:51
User entered 'No (N)'	System	23 Apr 2021 19:56:51

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-04-23T14:56:46-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '00831343-07e4-437f-b42a-34a358d3142f'	System	23 Apr 2021 19:56:51
User entered 'No (N)'	System	23 Apr 2021 19:56:51

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-04-23T14:56:47-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: '00831343-07e4-437f-b42a-34a358d3142f'	System	23 Apr 2021 19:56:51
User entered '23 Apr 2021 14:56:47'	System	23 Apr 2021 19:56:51

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

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 (ffb3c6f8085e76a6)', Time: '2021-04-30T17:10:14-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e6ea62ee-e3c7-45e4-b833-7a85342a7fb2'	System	30 Apr 2021 22:15:48
User entered 'No (N)'	System	30 Apr 2021 22:15:48

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Have you been exposed to someone with 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 (ffb3c6f8085e76a6)', Time: '2021-04-30T17:10:16-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e6ea62ee-e3c7-45e4-b833-7a85342a7fb2'	System	30 Apr 2021 22:15:48
User entered 'No (N)'	System	30 Apr 2021 22:15:48

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-04-30T17:10:18-05:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e6ea62ee-e3c7-45e4-b833-7a85342a7fb2'	System	30 Apr 2021 22:15:48
User entered '30 Apr 2021 17:10:18'	System	30 Apr 2021 22:15:48

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:19:47

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:19:47

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US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:19:47

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710040

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710042

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710046

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710048

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:19:47

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710050

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710060

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:19:47

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710089

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:19:47

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710098

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:19:47

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710100

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:19:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710113

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710123

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:19:47

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:19:47

FDA-CBER-2022-1614-0710132

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:19:47

US3252020

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:10:19

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:19:47

US3252020
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:10:19
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:47
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:19:47

US3252020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:10:19

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 15:00:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-03-01T13:52:52-06:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e5714c93-0ebc-4bca-91dd-a75e9e6f4646'	System	01 Mar 2021 19:52:59
User entered 'No (N)'	System	01 Mar 2021 19:52:59

US3252020

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:10:19

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:00:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffb3c6f8085e76a6)', Time: '2021-03-01T13:52:55-06:00', User OID: 'PatientReportedOutcome (US3252020)', ODM File OID: 'e5714c93-0ebc-4bca-91dd-a75e9e6f4646'	System	01 Mar 2021 19:52:59
User entered '01 Mar 2021 13:52:55'	System	01 Mar 2021 19:52:59

US3252020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Oct 2020 01:51:15
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '28 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 01:51:15

US3252020

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 01:51:15

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	Nancy Torrence (b) (4)	29 Oct 2020 01:51:15
	(b) (4)	

US3252020

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	29 Oct 2020 01:51:19
	(b) (4)	

US3252020
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:20:49
User entered '1'	System	29 Oct 2020 01:51:19

US3252020
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:02

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '2 Dec 2020'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:02

US3252020

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Contact Not Made (CONTACT NOT MADE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:02

US3252020
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'left voice mail'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:02

US3252020
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:15

US3252020
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered '1'	System	05 Feb 2021 03:03:15

US3252020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:42

US3252020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered '4 Jan 2021'	Joanna Gurrola Mahoney	05 Feb 2021 03:03:42
	(b) (4)	

US3252020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Contact Not Made (CONTACT NOT MADE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:42

US3252020

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'left voice mail'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:42

US3252020

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:03:46

US3252020
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered '1'	System	05 Feb 2021 03:03:46

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 05:16:55

FDA-CBER-2022-1614-0710157

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 05:16:55

US3252020
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 05:16:55

US3252020

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 05:16:55

US3252020
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 06:58:48
User entered 'Yes (Y)' reason for change: Data Entry Error		04 Mar 2021 06:58:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 05:17:01

US3252020
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered '1'	System	04 Mar 2021 06:58:48
User entered empty.	System	12 Feb 2021 05:17:01

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 07:00:40

FDA-CBER-2022-1614-0710163

US3252020
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 07:00:40

US3252020

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Mar 2021 07:00:40

US3252020
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered 'VISIT4'	System	04 Mar 2021 07:00:40

US3252020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 18:26:04

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '3 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 18:26:04

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '11:32'	(b) (4), (b) (6)	30 Mar 2021 18:26:04

US3252020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered '3 Mar 2021 11:32'	System	30 Mar 2021 18:26:04

US3252020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '98.7' F	(b) (4), (b) (6)	30 Mar 2021 18:26:04

US3252020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 18:26:04

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:26:04

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '59'	(b) (4), (b) (6)	30 Mar 2021 18:26:04

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered 'bpm'	System	30 Mar 2021 18:26:04

US3252020

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '15'	(b) (4), (b) (6)	30 Mar 2021 18:26:04

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered 'breaths/min'	System	30 Mar 2021 18:26:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '130'	(b) (4), (b) (6)	30 Mar 2021 18:26:04

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered 'mmHg'	System	30 Mar 2021 18:26:04

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '80'	(b) (4), (b) (6)	30 Mar 2021 18:26:04

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered 'mmHg'	System	30 Mar 2021 18:26:04

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22

US3252020
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22

US3252020

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 07:00:49

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 07:00:49

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 07:01:01

US3252020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 07:01:01

US3252020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 07:01:01

US3252020

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered empty.	System	04 Mar 2021 07:01:01

US3252020

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 07:01:10

US3252020
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:02:22
User entered '1'	System	04 Mar 2021 07:01:10

US3252020

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:08
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 03:13:29

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:08
User entered empty.	(b) (4), (b) (6)	03 May 2021 03:13:29

US3252020
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▩ (b) (4)	04 May 2021 00:27:08
User entered empty.	(b) (4), (b) (6) ▩	03 May 2021 03:13:29

US3252020
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:08
User entered empty.	(b) (4), (b) (6)	03 May 2021 03:13:29

US3252020

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 03:14:16

US3252020
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 03:14:16

US3252020
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▆(b) (4)	04 May 2021 00:27:08
User entered 'Yes (Y)'	▆(b) (4), (b) (6)▆	03 May 2021 03:16:31

Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

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

Audit	User		Time (GMT)
User signature succeeded.	Joel Solis	(b) (4)	04 May 2021 00:27:08
User entered '30 Apr 2021'	(b) (4), (b) (6)		03 May 2021 03:16:31

US3252020

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 May 2021 03:16:31

US3252020
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:08
User entered empty.	(b) (4), (b) (6)	03 May 2021 03:16:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	04 May 2021 00:27:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 03:17:01

FDA-CBER-2022-1614-0710202

US3252020

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	03 May 2021 03:17:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:10:19

Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:35
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Per ETRTR: Please complete Symtptoms Log that includes 17Aug20 and prior Symptoms Dates required for scheduling the Illness Visit Day 1, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 03:50:44
User closed query 'Per ETRTR: Please complete data entry for Illness Visit Day 1, Convalescent Visit and Saliva Collection Log entries, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 03:50:05
Query 'Per ETRTR: Please complete data entry for Illness Visit Day 1, Convalescent Visit and Saliva Collection Log entries, thanks.' answered with 'a progress note has been added to emr but please let me know how to input the symptoms patient had previously as in symptom log it starts with day 1. Will day one be the first day patient reported symptoms and if so only symptoms were collected but no pulse oximetry was done.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:12:28
Query 'Per ETRTR: Please complete Symtptoms Log that includes 17Aug20 and prior Symptoms Dates required for scheduling the Illness Visit Day 1, thanks.' answered with 'a progress note has been added to emr but please let me know how to input the symptoms patient had previously as in symptom log it starts with day 1. Will day one be the first day patient reported symptoms and if so only symptoms were collected but no pulse oximetry was done.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:12:24
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 01:48:10
User opened query 'Per ETRTR: Please complete data entry for Illness Visit Day 1, Convalescent Visit and Saliva Collection Log entries, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 22:10:11
User opened query 'Per ETRTR: Please complete Symtptoms Log that includes 17Aug20 and prior Symptoms Dates required for scheduling the Illness Visit Day 1, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 22:09:27
User entered '17 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:13:28

Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:35
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:19:55
User closed query 'The start time of the initial illness visit is unclear in source. Per the electronic source, the earliest assessment (Vitals) began at 14:50. Electronic source is not complete to show initial time of contact. Paper source that has been reviewed shows the time of contact at 17:00 on page 7/24. Please review and update as necessary. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:19:54
Query 'The start time of the initial illness visit is unclear in source. Per the electronic source, the earliest assessment (Vitals) began at 14:50. Electronic source is not complete to show initial time of contact. Paper source that has been reviewed shows the time of contact at 17:00 on page 7/24. Please review and update as necessary. ' answered with 'per paper source 7/17 patient was seen at 17:00' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:34:55
User entered '17:00' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:34:36
User opened query 'The start time of the initial illness visit is unclear in source. Per the electronic source, the earliest assessment (Vitals) began at 14:50. Electronic source is not complete to show initial time of contact. Paper source that has been reviewed shows the time of contact at 17:00 on page 7/24. Please review and update as necessary. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:04:14
Query 'The start time of the initial illness visit is unclear in source. Per the source, the earliest assessment (Vitals) began at 14:50. Source is not complete to show initial time of contact. Please review and update. ' canceled (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:00:39

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:10:19
Time of Contact

Audit	User	Time (GMT)
User opened query 'The start time of the initial illness visit is unclear in source. Per the source, the earliest assessment (Vitals) began at 14:50. Source is not complete to show initial time of contact. Please review and update. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 01:49:02
User entered '00:00'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:13:28

Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:35
User entered '17 Aug 2020 17:00'	System	29 Oct 2020 04:34:36
User entered '17 Aug 2020 00:00'	System	02 Sep 2020 15:13:28

FDA-CBER-2022-1614-0710207

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:10:19
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:35
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'In electronic source, the question "Was this visit performed at the participant's home or at the clinic?" is not answered, neither is the date and time of the visit. In the paper source provided, "type of contact" is listed as "Clinical visit-unscheduled" Please review source and reconcile for consistency.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:33:33
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:33:29
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:34:36
Query 'In electronic source, the question "Was this visit performed at the participant's home or at the clinic?" is not answered, neither is the date and time of the visit. In the paper source provided, "type of contact" is listed as "Clinical visit-unscheduled" Please review source and reconcile for consistency.' answered with 'per query electronic source was unable to capture this information therefore the paper source is correct Clinical VIsit UNS' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:34:26
Query 'in source, the question "Was this visit performed at the participant's home or at the clinic?" is not answered, neither is the date and time of the visit. Please review source and reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:06:55
User opened query 'In electronic source, the question "Was this visit performed at the participant's home or at the clinic?" is not answered, neither is the date and time of the visit. In the paper source provided, "type of contact" is listed as "Clinical visit-unscheduled" Please review source and reconcile for consistency.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:06:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:10:19
Type of Contact

Audit	User	Time (GMT)
Query 'In electronic source, the question "Was this visit performed at the participant's home or at the clinic?" is not answered, neither is the date and time of the visit. In the paper source provided, "type of contact" is listed as "Clinical visit-unscheduled" Please review source and reconcile for consistency.' canceled (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:06:16
User opened query 'In electronic source, the question "Was this visit performed at the participant's home or at the clinic?" is not answered, neither is the date and time of the visit. In the paper source provided, "type of contact" is listed as "Clinical visit-unscheduled" Please review source and reconcile for consistency.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:06:14
User opened query 'in source, the question "Was this visit performed at the participant's home or at the clinic?" is not answered, neither is the date and time of the visit. Please review source and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:57:20
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 16:56:42
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 01:49:05
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:13:28

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:10:19

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:35
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:49:09
Query '"Has the subject reported symptoms of SARS-COV-2" is not a question that is directly indicated in the source, nor is there a source note to provide clarification. Please review and update source if necessary so this can be verified. ' canceled (Site from CRA).		27 Oct 2020 17:49:07
User opened query '"Has the subject reported symptoms of SARS-COV-2" is not a question that is directly indicated in the source, nor is there a source note to provide clarification. Please review and update source if necessary so this can be verified. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 01:50:26
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 01:49:18
DataPoint Verified.		22 Oct 2020 01:49:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:53:01
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:16:25
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:13:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
Query 'Source provided for day 1 symptom log is for the subject US3252075. Please provide correct source. ' canceled (Site from CRA).		22 Oct 2020 16:53:12
User opened query 'Source provided for day 1 symptom log is the subject US3252075. Please provide correct source. ' (Site from CRA).		22 Oct 2020 02:04:11
User entered 'Day 1 (Day 1)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:52
User closed query 'Per CDM: Please confirm that initial start date of symptoms and Contact Date are the same (17AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:55:02
Query 'Per CDM: Please confirm that initial start date of symptoms and Contact Date are the same (17AUG2020) or update accordingly' answered with 'Updated.' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:29
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered '13 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User opened query 'Per CDM: Please confirm that initial start date of symptoms and Contact Date are the same (17AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:12:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:15
User entered '17 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:19

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:17
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:41:11
User closed query 'Per CDM: It appears that O2 Saturation and temperature were not provided for days 1 - 4. If not collected, please consider recording as Not Done.	(b) (4), (b) (6)	08 Feb 2021 16:39:20
' (Site from DM). Query 'Per CDM: It appears that O2 Saturation and temperature were not provided for days 1 - 4. If not collected, please consider recording as Not Done.	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 04:00:28
' answered with 'updated' (Site from DM). DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 04:00:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 04:00:12
User opened query 'Per CDM: It appears that O2 Saturation and temperature were not provided for days 1 - 4. If not collected, please consider recording as Not Done.	(b) (4), (b) (6)	11 Jan 2021 17:36:12
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:34
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:21
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered '%'	System	08 Feb 2021 04:00:12
User entered empty.	System	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 19:17:58

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:19

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:41:09
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 04:00:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 04:00:12
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:36
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:23
User entered '99.1' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:37
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:30
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:39
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:42
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:19

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:47
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:39
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:22:53
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:41
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:09
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:19

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:42
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:13
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:44
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:17
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:10:19

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:28
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:45
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:32
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:47
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:35
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:39
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:41
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:45
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:26:49
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:24:48
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:17:58

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 2 (Day 2)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:28
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered '14 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:04:38
User entered '18 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:32
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:17
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 05:43:53
User entered '1' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 16:47:31
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:27:53
User closed query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 10:09:29
Query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' answered with 'UPDATED' (Site from DM).	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:43:54
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:43:44
User opened query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:40:05
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:18
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:14
User entered '99'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered '%'	System	12 Feb 2021 06:43:44
User entered empty.	System	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 19:21:06

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:27:55
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:43:44
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:20
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:17
User entered '98.9' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:35
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:22
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:21
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:37
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:24
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:28
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:38
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:25
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:33
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:40
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:27
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:37
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:41
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:29:15
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:40
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:42
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:28:03
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:45
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:44
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:28:05
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:05:55
User entered 'Not Done (Not Done)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:45
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:28:00
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:18
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:33:47
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:58
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:21
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:34:12
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:56
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:25
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:34:18
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:54
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:31
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:34:20
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:42
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:34
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:34:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:40
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:40
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:34:56
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:39
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:42
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:34:58
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:37
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:44
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:10:19

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:34:59
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 16:13:46
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:27:35
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 02:13:49
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:21:06

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 3 (Day 3)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:39:10
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered '15 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:34:25
User entered '19 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

FDA-CBER-2022-1614-0710256

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:34:27
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:19

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:27:27
User closed query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 10:09:38
Query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' answered with 'UPDATED' (Site from DM).	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:12
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:06
User entered missing code ND - Not Done; reason for change Data Entry Error	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:06
User opened query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:40:17
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:05
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:34:38
User entered '99'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered '%'	System	12 Feb 2021 06:44:06
User entered empty.	System	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 19:24:35

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:27:28
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:06
User entered missing code ND - Not Done; reason for change Data Entry Error	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:06
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:06
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:36:36
User entered '98.6' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

FDA-CBER-2022-1614-0710260

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:09
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:36:39
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

FDA-CBER-2022-1614-0710261

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User closed query 'In the paper source that is uploaded, "cough" severity is not completed. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 03:50:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Nov 2020 00:50:29
Query 'In the paper source that is uploaded, "cough" severity is not completed. Please review and reconcile. ' answered with 'Paper source with late entry has been uploaded. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:50:04
User opened query 'In the paper source that is uploaded, "cough" severity is not completed. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:37:27
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:37:31
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:37:34
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:20
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:37:51
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:22
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:38:04
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:23
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:38:52
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:24
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 05:43:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:38:55
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:38:58
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:39:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:26
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:39:04
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:36:27
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:43:53
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:39:09
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:39:13
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:39:21
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:39:29
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:10:19

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:39:38
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:24:35

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 4 (Day 4)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:39:13
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered '16 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:52:09
User entered '20 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

FDA-CBER-2022-1614-0710278

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:39:30
DataPoint Un-verified.		21 Nov 2020 17:39:15
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:52:14
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:19

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:27:19
User closed query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 10:09:45
Query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' answered with 'UPDATED' (Site from DM).	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:29
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:24
User entered missing code ND - Not Done; reason for change Data Entry Error	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:24
User opened query 'Per CDM: It appears that O2 Saturation and temperature were not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:40:26
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:39:17
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:53:58
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered '%'	System	12 Feb 2021 06:44:24
User entered empty.	System	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 19:27:01

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:19

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:27:21
DataPoint Un-verified.	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:24
User entered missing code ND - Not Done; reason for change Data Entry Error	mathew maran (b) (4) (b) (4)	12 Feb 2021 06:44:24
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:39:18
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:00
User entered '97' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:03
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:07
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:09
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:19

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:14
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:39:24
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:18
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:27
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:30
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:35
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:39
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:44
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:47
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:51
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:54:59
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:55:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:55:08
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:27:01

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 5 (Day 5)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:19

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:40:08
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered '17 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:57:54
User entered '21 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:57:57
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:40:13
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered '98' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:57:59
User entered '99'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:40:14
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered '99.1' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:01
User entered '98.7' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:40:33
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:06
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:08
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:14
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:41:02
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:16
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:41:06
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 05:53:09
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:19
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:41:11
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:41:18
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:26
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:30
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:35
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:40
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:41:37
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 05:53:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:58:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:59:00
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:59:03
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:59:06
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

FDA-CBER-2022-1614-0710319

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:41:40
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 05:53:09
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 17:59:08
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:55:12

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 6 (Day 6)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:10:19

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:50:03
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
User entered '18 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:17:48
User entered '22 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:17:50
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:52:19
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '99' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:17:56
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

FDA-CBER-2022-1614-0710324

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:52:18
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '98.9' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:17:57
User entered '98.1' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:17:59
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:52:21
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:01
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:09
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:52:32
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:13
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:52:47
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:16
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:21
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:52:56
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

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New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:29
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:38
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:53:15
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:44
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:53:23
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:48
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:52
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:54
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:55
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:18:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:57:28

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 7 (Day 7)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:53:37
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '19 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:21:10
User entered '23 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:19

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:24:37
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:53:49
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '99' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:24:48
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:53:50
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '98.6' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:24:49
User entered '97.9' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:53:53
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:53:56
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:04
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:09
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:54:02
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:14
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:54:05
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:18
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:56:25
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:56:27
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:19

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:31
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:37
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:56:32
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:41
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:56:35
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:46
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:49
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:52
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:54
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:25:58
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 21:59:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 8 (Day 8)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:56:55
User entered '20 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User closed query 'In source for Visit Day 8, the Covid-19 Contact date is 24AUG2020, however the symptom log day is dated 25AUG2020, as well as the section for "Daily Telemedicine Visit" is also dated 25AUG2020. Please review and clarify source for the date that of this assessment. ' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 03:51:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
Query 'In source for Visit Day 8, the Covid-19 Contact date is 24AUG2020, however the symptom log day is dated 25AUG2020, as well as the section for "Daily Telemedicine Visit" is also dated 25AUG2020. Please review and clarify source for the date that of this assessment. ' answered with 'this has been corrected.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:54:54
User opened query 'In source for Visit Day 8, the Covid-19 Contact date is 24AUG2020, however the symptom log day is dated 25AUG2020, as well as the section for "Daily Telemedicine Visit" is also dated 25AUG2020. Please review and clarify source for the date that of this assessment. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:10:08
Query 'Entries for this page in source are all dated 25AUG2020. Please review and confirm if assessments were completed on this date. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:09:00
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 18:08:47
DataPoint Verified.		27 Oct 2020 18:01:55
User opened query 'Entries for this page in source are all dated 25AUG2020. Please review and confirm if assessments were completed on this date. ' (Site from CRA).		22 Oct 2020 18:33:05

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Date

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:19

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:17
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:08:49
DataPoint Verified.		27 Oct 2020 18:05:09
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710368

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:15
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:08:50
DataPoint Verified.		27 Oct 2020 18:05:12
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710369

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:19
User entered '97' F reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:08:54
DataPoint Verified.		27 Oct 2020 18:05:15
User entered '98.1' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:21
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:08:56
DataPoint Verified.		27 Oct 2020 18:05:19
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:08:57
DataPoint Verified.		27 Oct 2020 18:05:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710373

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:25
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:10
DataPoint Verified.		27 Oct 2020 18:05:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:30
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:11
DataPoint Verified.		27 Oct 2020 18:05:25
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710375

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:13
DataPoint Verified.		27 Oct 2020 18:05:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:36
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:14
DataPoint Verified.		27 Oct 2020 18:05:30
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:38
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:15
DataPoint Verified.		27 Oct 2020 18:05:32
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:17
DataPoint Verified.		27 Oct 2020 18:05:35
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:47
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:19
DataPoint Verified.		27 Oct 2020 18:05:37
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710380

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:50
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:20
DataPoint Verified.		27 Oct 2020 18:05:38
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710381

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:53
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:22
DataPoint Verified.		27 Oct 2020 18:05:44
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710382

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:58:57
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:23
DataPoint Verified.		27 Oct 2020 18:05:47
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710383

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:59:00
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:24
DataPoint Verified.		27 Oct 2020 18:05:49
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710384

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:59:02
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:26
DataPoint Verified.		27 Oct 2020 18:05:51
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:10:19

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:59:04
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:27
DataPoint Verified.		27 Oct 2020 18:05:53
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 17:59:07
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Un-verified.		27 Oct 2020 18:10:29
DataPoint Verified.		27 Oct 2020 18:05:55
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:01:46

FDA-CBER-2022-1614-0710387

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 9 (Day 9)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:56:05
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '21 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:34:19
User entered '25 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

FDA-CBER-2022-1614-0710389

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:19

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:22
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:56:09
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '99' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:20
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:56:11
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '98.7' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:24
User entered '98.1' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:19

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:56:14
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:27
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

FDA-CBER-2022-1614-0710395

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:31
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

FDA-CBER-2022-1614-0710396

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:37
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:40
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:45
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

FDA-CBER-2022-1614-0710399

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:48
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:56:43
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:50
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:56:48
DataPoint Un-verified.		11 Nov 2020 15:56:46
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:51
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

FDA-CBER-2022-1614-0710402

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:54
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:44:59
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:45:03
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:45:07
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:45:10
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:45:12
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:45:15
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:03:50

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:19

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 10 (Day 10)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:57:21
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '22 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:13
User entered '26 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:16
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:20
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

FDA-CBER-2022-1614-0710413

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 22:05:41

FDA-CBER-2022-1614-0710414

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:57:28
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered '98.1' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:23
User entered '97.8' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:38
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:57:37
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:39
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

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Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:41
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:19

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:43
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:48
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:50
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:19

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:52
	rockytrevino1)	
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:54
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:55
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:48:59
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:49:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:10:19

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:49:04
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:49:06
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:49:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:58:15
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:05:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:49:12
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:05:41

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 11 (Day 11)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:58:34
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
User entered '23 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:05
User entered '27 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:07
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:08
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

FDA-CBER-2022-1614-0710435

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 22:07:34

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:19

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:58:43
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
User entered '97.9' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:11
User entered '97.6' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:13
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:20
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:25
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

FDA-CBER-2022-1614-0710440

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:27
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:31
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:35
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:19

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:38
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:41
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:19

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:48
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:56:59
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:57:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:57:07
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:57:13
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:57:16
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:10:19

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:57:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:59:32
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:57:25
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:07:34

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 12 (Day 12)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:59:45
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 06:59:49
User entered '24 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:57:56
User entered '28 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:19

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:00
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:04
User entered '98'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 22:10:19

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:19

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:59:57
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
User entered '98.1' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:07
User entered '97.5' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:12
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:00:23
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:14
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:17
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:21
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:30
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:58:41
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:59:55
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 18:59:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:07
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:18
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:16
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:14
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:21
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:10:19

FDA-CBER-2022-1614-0710475

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
User entered 'Day 13 (Day 13)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

FDA-CBER-2022-1614-0710476

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:08:25
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '25 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:40
User entered '29 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:43
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:08:28
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '98' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:45
User entered '96'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
DataPoint activated with code reason code Data required.		05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
User entered '%'	System	21 Oct 2020 22:12:13

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:19

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:47
User entered '98.1' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:52
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:08:34
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:00:56
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:01:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:19

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:01:06
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:01:08
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:01:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:01:15
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:01:18
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:01:21
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

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US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:02:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:02:04
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:02:16
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:02:19
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:02:21
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:02:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:02:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:12:13

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:19

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 14 (Day 14)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:40
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 07:04:47
User entered '26 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:10:25
DataPoint Un-verified.		22 Oct 2020 19:10:11
DataPoint Verified.		22 Oct 2020 19:04:02
User entered '30 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:42
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '0' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:48:57
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:08:12
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 18:21:25
DataPoint Verified.		22 Oct 2020 19:10:27
DataPoint Un-verified.		22 Oct 2020 19:10:13
DataPoint Verified.		22 Oct 2020 19:04:03
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:12
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '98' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:04:08
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered '%'	System	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered empty.	System	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:14
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '97.8' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		22 Oct 2020 19:04:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:19

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:16
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:48:54
User closed query 'Per source, severity assessment is not completed for symptoms. Please confirm if you can change the answer to "Not Done". ' (Site from CRA).		05 Nov 2020 00:48:52
Query 'Per source, severity assessment is not completed for symptoms. Please confirm if you can change the answer to "Not Done". ' answered with 'this has been completed for all. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User opened query 'Per source, severity assessment is not completed for symptoms. Please confirm if you can change the answer to "Not Done". ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:09:14
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:04:58
DataPoint Verified.		22 Oct 2020 19:04:31
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:20
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
User closed query 'Per source, severity assessment is not completed for any symptoms. Please confirm if you can change the answer to "Not Done" and reevaluate the answers below. ? ' (Site from CRA).		05 Nov 2020 00:49:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 00:48:59
Query 'Per source, severity assessment is not completed for any symptoms. Please confirm if you can change the answer to "Not Done" and reevaluate the answers below. ? ' answered with 'this has been completed for all. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User opened query 'Per source, severity assessment is not completed for any symptoms. Please confirm if you can change the answer to "Not Done" and reevaluate the answers below. ? ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:09:43
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:05:00
DataPoint Verified.		22 Oct 2020 19:04:34
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:24
DataPoint Un-verified.	Shannon Moyer (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:01
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:05:02
DataPoint Verified.		22 Oct 2020 19:04:38
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:19

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:27
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:04
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:05:04
DataPoint Verified.		22 Oct 2020 19:04:50
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:29
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:06
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:05:06
DataPoint Verified.		22 Oct 2020 19:04:52
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:31
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:08
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 19:05:08
DataPoint Verified.		22 Oct 2020 19:04:54
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:34
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:37
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:41
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:12
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:44
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:47
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:51
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:58
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:56
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:54
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:10:53
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:13:18

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered 'Day 15 (Day 15)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

FDA-CBER-2022-1614-0710520

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:23
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '27 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		27 Oct 2020 18:24:02
User entered '31 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

FDA-CBER-2022-1614-0710521

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:19

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:25
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '0' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:35
User closed query 'Per source, the symptom assessment is disabled and no data is collected. Please review EDC responses and consider if this assessment should be marked "not done"' (Site from CRA).		05 Nov 2020 00:49:33
Query 'Per source, the symptom assessment is disabled and no data is collected. Please review EDC responses and consider if this assessment should be marked "not done"' answered with 'this has been completed for all. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:08:05
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:07:58
User opened query 'Per source, the symptom assessment is disabled and no data is collected. Please review EDC responses and consider if this assessment should be marked "not done"' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:27:06
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:31
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '98' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:37
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered '%'	System	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
User entered empty.	System	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:33
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered '97.6' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:38
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:37
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:40
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:56
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:11:58
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:12:00
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:12:02
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:47
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:41
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:48
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:44
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:46
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:48
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:52
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:52
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:53
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:56
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:16:59
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:00
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:49:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:02
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:50:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:03
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:50:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:17:05
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29
DataPoint Verified.		05 Nov 2020 00:50:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:09:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:15:48

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:10:19

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:04:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:43:48
User closed query 'Per source 28AUG2020, please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:43:45
Query 'Per source 28AUG2020, please review and reconcile. ' answered with 'updated.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 17:56:07
User entered '28 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	14 Nov 2020 17:55:54
User opened query 'Per source 28AUG2020, please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:30:24
User entered '29 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:32
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 07:08:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 07:08:45
User entered '29 Oct 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 06:59:49
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:43:49
User entered '0'	Shannon Moyer (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:07
User entered '98' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered '%'	System	09 Nov 2020 07:08:45
User entered empty.	System	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:10
User entered '97.5' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:12
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:18
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:20
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:22
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:25
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:29
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:31
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:33
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29

FDA-CBER-2022-1614-0710556

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:36
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:42
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:45
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:47
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:50
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data no required.		05 Nov 2020 00:50:29

FDA-CBER-2022-1614-0710561

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:54
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:57
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:01
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:35:11
User entered '29 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:32
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 07:08:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 07:08:45
User entered '29 Oct 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 06:59:49
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:10:19

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:35:13
User entered '0'	Shannon Moyer (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:35:17
User entered '96' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered '%'	System	09 Nov 2020 07:08:45
User entered empty.	System	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:10:19

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:35:20
User entered '98.1' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:35:54
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:36:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:10:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:13
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:16
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

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US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:24
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:27
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:28
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:31
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:34
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:36
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

FDA-CBER-2022-1614-0710580

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:44
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:51
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:54
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:10:19

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:56
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:43:58
User entered 'None (None)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:08:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 06:59:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 00:50:50
DataPoint inactivated with code reason code Data not required.		05 Nov 2020 00:50:29

FDA-CBER-2022-1614-0710585

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Day 18 (Day 18)'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:04
User entered '30 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:32
User entered '30 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:15
User entered '1'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered empty.	System	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:19
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:09:19
	(b) (4)	

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:22
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:24
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:26
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:09:19
	(b) (4)	

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:10:19

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:28
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:09:19
	(b) (4)	

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:30
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:32
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:34
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:35
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:39
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:41
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:09:19
	(b) (4)	

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:42
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:09:19
	(b) (4)	

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:48
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:44:51
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:09:19

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Day 19 (Day 19)'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:11
User entered '31 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:12
User entered '1'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:15
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User entered empty.	System	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:19
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:21
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:24
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:26
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:30
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:31
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:34
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:36
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:10:56
	(b) (4)	

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:37
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:10:56
	(b) (4)	

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:39
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:10:56
	(b) (4)	

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:41
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:10:56
	(b) (4)	

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:43
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:45
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:48
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:10:56

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:10:19
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:42
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:45:50
User entered empty.	Shannon Moyer (b) (4)	09 Nov 2020 07:10:56
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 17AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 17AUG2020 for this subject then update the Preclarus. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 11:30:23
Query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 17AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 17AUG2020 for this subject then update the Preclarus. Thank you. ' answered with 'Saliva sample was also collected along with the Swab sample' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 06:33:34
User opened query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 17AUG2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 17AUG2020 for this subject then update the Preclarus. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 02:55:31
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:32:28
User entered '17 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:10:19

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:32:31
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:19

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
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)	09 Nov 2020 02:12:37
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:32:37
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'test result was positive and ae page was updated' (Site from System).	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:23:58
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	21 Oct 2020 22:20:58
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:10:19
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:32:52
User entered '17 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:10:19
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:32:54
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:10:19
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:32:58
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:10:19

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:33:02
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:10:19

Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:33:05
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:10:19
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:33:06
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:20:58

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:10:19

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:49
User entered '1'	System	21 Oct 2020 22:20:58

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:19

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis　(b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:37
User entered 'No (N)'	Joanna Gurrola Mahoney　(b) (4)	21 Oct 2020 22:25:07

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:19

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:49
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

FDA-CBER-2022-1614-0710644

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:19

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)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:19

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19

High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

FDA-CBER-2022-1614-0710662

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19

Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:19

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19

Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19

Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:19

Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19

Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020

Folder: Covid-19 Assessment 17 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:10:19

Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:10:19
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:29:55
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:36:51
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:25:07

US3252020
Folder: Covid-19 Assessment 17 Aug 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:10:19
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:30:01
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:35:50
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:50:26
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:16:44

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19,21,23,25AUG2020 is recorded under Illness Visit Day 3,5,7,9 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. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 02:54:46
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19,21,23,25AUG2020 is recorded under Illness Visit Day 3,5,7,9 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 06:19:12
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:10:56
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Day 1 was on 17-AUG-2020 and day 3 saliva collection was collected on 19-AUG-2020 as entered. Initial date is correct' (Site from DM).	Xavier Morales (b) (4) (b) (4)	12 Nov 2020 23:39:19
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:23:52

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:10:19

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:10:19

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓ (b) (4)	28 Apr 2021 11:32:22
DataPoint Verified.	(b) (4), (b) (6) ▓	22 Oct 2020 17:42:36
User entered 'Yes (Y)'	Joanna Gurrola Mahoney ▓ (b) (4)	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:10:19

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
User closed query 'Per GCL Lab Reconciliation: Swab sample for Visit 2 Day 29 has been received by Central Lab with date 17Sep 2020. However Visit 2 Day 29 has not been filled out please confirm and update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:11:02
Query 'Per GCL Lab Reconciliation: Swab sample for Visit 2 Day 29 has been received by Central Lab with date 17Sep 2020. However Visit 2 Day 29 has not been filled out please confirm and update accordingly.' answered with 'day 29 has been entered into EDC. ' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:42:17
User opened query 'Per GCL Lab Reconciliation: Swab sample for Visit 2 Day 29 has been received by Central Lab with date 17Sep 2020. However Visit 2 Day 29 has not been filled out please confirm and update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 13:35:44
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:42:38
User entered '19 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:10:19

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:10:19

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
Data hard locked.	(b) (4), (b) (6)	28 Feb 2021 05:18:26
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:43:11
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:10:19
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 21AUG2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F623698532) is reported. Hence please confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 06:35:09
Query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 21AUG2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F623698532) is reported. Hence please confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' answered with 'Sample day 7 1F600117292 and all others have been shipped out and received since 27AUG2020 AWB number is 906907881486.' (Site from DM).	mathew maran (b) (4) (b) (4)	03 Mar 2021 06:10:28
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 21AUG2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F623698532) is reported. Hence please confirm correct date of collection for Day 5 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 05:19:47
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:51:23
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' answered with 'Accession number is 1F623708836. Saliva sample was shipped out with AWB 906907881512.' (Site from DM).	mathew maran (b) (4) (b) (4)	11 Feb 2021 03:52:59
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:32:49

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:10:19

Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 21AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:32:49
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 21AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'the sample has been collected ' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 11:43:21
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 21AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 02:56:26
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:43:13
User entered '21 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:10:19

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

FDA-CBER-2022-1614-0710700

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:10:19

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ████ (b) (4)	28 Apr 2021 11:32:22
DataPoint Verified.	(b) (4), (b) (6) ████	22 Oct 2020 17:43:38
User entered 'Yes (Y)'	Joanna Gurrola Mahoney ███ (b) (4) ███	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:10:19

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
User closed query 'Per GCL Lab Reconciliation: Saliva Re-query : For Day 7, EDC Sample date is 23AUG2020, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F600117292) is reported. Please note that the collection date should be same in the EDC and Preclarus report. Hence please confirm the correct date in the response for the Day 7 and update accordingly in Preclarus .' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:28:29
Query 'Per GCL Lab Reconciliation: Saliva Re-query : For Day 7, EDC Sample date is 23AUG2020, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F600117292) is reported. Please note that the collection date should be same in the EDC and Preclarus report. Hence please confirm the correct date in the response for the Day 7 and update accordingly in Preclarus .' answered with 'Sample day 7 1F600117292 and all others have been shipped out and received since 27AUG2020 AWB number is 906907881486. site could not upload the documents as separate. hence uploaded on the single date.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 05:16:48
User opened query 'Per GCL Lab Reconciliation: Saliva Re-query : For Day 7, EDC Sample date is 23AUG2020, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F600117292) is reported. Please note that the collection date should be same in the EDC and Preclarus report. Hence please confirm the correct date in the response for the Day 7 and update accordingly in Preclarus .' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:40:40
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:30:29

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:10:19

Date of Collection

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' answered with 'Sample day 7 1F600117292 and all others have been shipped out and received since 27AUG2020 AWB number is 906907881486.' (Site from DM).	mathew maran (b) (4) (b) (4)	03 Mar 2021 06:10:35
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:32:55
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 23AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:32:55
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 23AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'task sent to crio' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 11:44:32
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 23AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 02:56:50
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:43:50
User entered '23 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:10:19
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:35
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

FDA-CBER-2022-1614-0710705

US3252020
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:10:19
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 11:34:56
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' answered with 'Accession Number: 1F63149' (Site from DM).	mathew maran (b) (4) (b) (4)	01 Mar 2021 10:36:27
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:33:00
User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 25AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:33:00
Query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 25AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'task has been sent to source' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 11:43:52
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 25AUG2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 02:57:18
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:37
User entered '25 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:10:19
Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:10:19

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis　(b) (4)	28 Apr 2021 11:32:22
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:23:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:24:08
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 14, EDC Sample Collected is No, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F617400868) is reported. Hence please confirm correct date of collection for Day14 and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:39:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 05:22:23
Query 'Per GCL Lab Reconciliation: Saliva : For Day 14, EDC Sample Collected is No, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F617400868) is reported. Hence please confirm correct date of collection for Day14 and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 05:57:51
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 05:57:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 05:57:45
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 14, EDC Sample Collected is No, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F617400868) is reported. Hence please confirm correct date of collection for Day14 and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:07:02
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:28:24

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:10:19

Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Please confirm if saliva sample was collected on Day 14. Source states that it was collected, however there are no lab results available. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 01:28:20
Query 'Please confirm if saliva sample was collected on Day 14. Source states that it was collected, however there are no lab results available. ' answered with 'samples were not collected.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:41:34
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:41:26
User opened query 'Please confirm if saliva sample was collected on Day 14. Source states that it was collected, however there are no lab results available. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:35:07
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:10:19
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 14, EDC Sample Collected is No, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F617400868) is reported for Day 14. Hence please "confirm correct date of collection for Day14" and update EDC or PPD Central lab. "Please note that the collection details are required to be recorded for the subject irrespective of the results". Else please review the Accession # 1F617400868 and confirm the sample details.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:16:36
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:23:28
Query 'Per GCL Lab Reconciliation: Saliva : For Day 14, EDC Sample Collected is No, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F617400868) is reported for Day 14. Hence please "confirm correct date of collection for Day14" and update EDC or PPD Central lab. "Please note that the collection details are required to be recorded for the subject irrespective of the results". Else please review the Accession # 1F617400868 and confirm the sample details.' answered with 'All saliva samples were received at PPD since August. I have updated the collection dates' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:25:19
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:24:08
User entered '30 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:24:08
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 14, EDC Sample Collected is No, however in PPD Central Lab sample dated 17AUG2020 (Accession # 1F617400868) is reported for Day 14. Hence please "confirm correct date of collection for Day14" and update EDC or PPD Central lab. "Please note that the collection details are required to be recorded for the subject irrespective of the results". Else please review the Accession # 1F617400868 and confirm the sample details.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:43:40

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:10:19

Date of Collection

Audit	User	Time (GMT)
User closed query 'It's noted sample was not collected on this day. Should date of collection be updated? ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:57:35
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:57:33
Query 'It's noted sample was not collected on this day. Should date of collection be updated? ' answered with 'Corrected.' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:14:17
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:13:59
User opened query 'It's noted sample was not collected on this day. Should date of collection be updated? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 01:28:57
User entered '30 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:10:19
Visit

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is NA, however in PPD Central Lab sample dated 17AUG2020(Accession # 1F600046178) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:17:08
Query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is NA, however in PPD Central Lab sample dated 17AUG2020(Accession # 1F600046178) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results.' answered with 'Saliva sample was collected for this patient/day' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:26:06
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 28, EDC Sample Collected is NA, however in PPD Central Lab sample dated 17AUG2020(Accession # 1F600046178) is reported. Hence please confirm correct date of collection for Day 28 and update EDC or PPD Central lab. Please note that the collection details are required to be recorded for the subject irrespective of the results.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:08:05
User accepted default value 'Day 21 (Day 21)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:10:19
Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva : PPD Central Lab Day 28 reported as 17aug2020. Please confirm the correct date to be update in the PPD Central Lab for Day 21.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 07:07:32
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
Query 'Per GCL Lab Reconciliation: Saliva : PPD Central Lab Day 28 reported as 17aug2020. Please confirm the correct date to be update in the PPD Central Lab for Day 21.' answered with 'The collection date is generalized for the start of the D3 illness visit due to the requisition form containing saliva samples D3-D21' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 06:20:20
User opened query 'Per GCL Lab Reconciliation: Saliva : PPD Central Lab Day 28 reported as 17aug2020. Please confirm the correct date to be update in the PPD Central Lab for Day 21.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 16:21:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:23:52
User closed query 'If not collected the answer should be NO not NA. NA is only for subjects who were negative at Illness Day 1 per protocol.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:25:06
Query 'If not collected the answer should be NO not NA. NA is only for subjects who were negative at Illness Day 1 per protocol.' answered with 'It was an error, saliva sample was collected' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:25:50
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:24:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:24:08
User opened query 'If not collected the answer should be NO not NA. NA is only for subjects who were negative at Illness Day 1 per protocol.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 23:08:26
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 14:26:57
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 03:45:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 03:45:18

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:10:19

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:29:15
User closed query 'Per protocol, subject should have had saliva sample collected on day 21. Please confirm if "Not done" can be selected for this response. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 01:29:13
Query 'Per protocol, subject should have had saliva sample collected on day 21. Please confirm if "Not done" can be selected for this response. ' answered with 'saliva sample not collected' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:53:32
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:53:22
User opened query 'Per protocol, subject should have had saliva sample collected on day 21. Please confirm if "Not done" can be selected for this response. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:35:58
User entered 'NA (COVID-19 Negative) (NA)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:10:19

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:23:51
User entered '06 Sep 2020' reason for change: New Information	mathew maran (b) (4) (b) (4)	15 Apr 2021 02:34:11
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:24:08
User entered '30 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	12 Apr 2021 14:24:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:29:16
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:10:19

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:10:19
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:24:20
User closed query 'If not collected the answer should be NO not NA. NA is only for subjects who were negative at Illness Day 1 per protocol.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:24:15
Query 'If not collected the answer should be NO not NA. NA is only for subjects who were negative at Illness Day 1 per protocol.' answered with 'updated' (Site from CRA).	mathew maran (b) (4) (b) (4)	14 Apr 2021 03:36:06
User entered 'No (N)' reason for change: Data Entry Error	mathew maran (b) (4) (b) (4)	14 Apr 2021 03:35:50
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 20:39:38
User opened query 'If not collected the answer should be NO not NA. NA is only for subjects who were negative at Illness Day 1 per protocol.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:25:34
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 14:27:24
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 03:45:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 03:45:18
User closed query 'Per protocol, subject should have had saliva sample collected on day 28. Please confirm if "Not done" can be selected for this response. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 01:29:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:29:23
Query 'Per protocol, subject should have had saliva sample collected on day 28. Please confirm if "Not done" can be selected for this response. ' answered with 'saliva sample not collected.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:53:46
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:53:37
User opened query 'Per protocol, subject should have had saliva sample collected on day 28. Please confirm if "Not done" can be selected for this response. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 18:36:18
User entered 'NA (COVID-19 Negative) (NA)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

FDA-CBER-2022-1614-0710717

US3252020

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:10:19

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:32:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:29:26
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:52:21

US3252020
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:37
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:26:04

FDA-CBER-2022-1614-0710719

US3252020
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:39
User entered '17 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:26:04

US3252020
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:41
User entered 'Clinic (Clinic)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:26:04

US3252020
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User entered 'SICKD1'	System	21 Oct 2020 22:26:04

US3252020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:02
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:06
User entered '17 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:07
User entered '15:00'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User entered '17 Aug 2020 15:00'	System	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:14
User entered '70.5' in	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17
DataPoint set to visible.	System	21 Oct 2020 22:26:04

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:19
User entered '190' lb	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17
DataPoint set to visible.	System	21 Oct 2020 22:26:04

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Per CDM: Temperature is not less than 38.0 C/100.4 F as required by protocol. Please review "unit of measurement for temperature' (centigrade, denoted C or, Fahrenheit denoted F), and update accordingly or, confirm temperature is correct.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:52:38
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:37:13
Query 'Per CDM: Temperature is not less than 38.0 C/100.4 F as required by protocol. Please review "unit of measurement for temperature' (centigrade, denoted C or, Fahrenheit denoted F), and update accordingly or, confirm temperature is correct.' answered with 'updated' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:22:55
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:22:40
User entered '99.1' F reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:22:40
User opened query 'Per CDM: Temperature is not less than 38.0 C/100.4 F as required by protocol. Please review "unit of measurement for temperature' (centigrade, denoted C or, Fahrenheit denoted F), and update accordingly or, confirm temperature is correct.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 21:13:53
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 19:03:56
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:34
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per PI' (Site from System).	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:37
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered '99.1' C	Joanna Gurrola Mahoney	21 Oct 2020 22:28:17
	(b) (4)	

US3252020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:37
User entered 'Oral (Oral)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:44
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:42
User entered '78'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User entered 'bpm'	System	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:54
User entered '16'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User entered 'breaths/min'	System	21 Oct 2020 22:28:17

US3252020

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis ▮(b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:57
User entered '145'	Joanna Gurrola Mahoney ▮(b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User entered 'mmHg'	System	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:29:59
User entered '91'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User entered 'mmHg'	System	21 Oct 2020 22:28:17

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57

US3252020
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57

US3252020

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:30:18
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:09

US3252020

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:30:22
User entered '17 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:09

US3252020

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:43:19
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:24

FDA-CBER-2022-1614-0710745

US3252020

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:10:19

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:36:57
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:43:21
User entered '17 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:24

US3252020

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:38
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:36

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▨ (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6) ▨	29 Oct 2020 21:39:38
User entered empty.	Joanna Gurrola Mahoney ▨ (b) (4)	21 Oct 2020 22:29:36

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:38
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:36

US3252020

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

Folder OID

Audit	User	Time (GMT)
User entered 'SICKD28'	System	21 Oct 2020 22:29:36

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Pulse units

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▒(b) (4)▒	26 Feb 2021 22:28:11
DataPoint Verified.	▒(b) (4), (b) (6)▒	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney ▒(b) (4)▒	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:42

US3252020
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 22:29:42

US3252020

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:46
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:48

US3252020

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:39:46
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:48

US3252020

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:33
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:56

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:49:33
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:29:56

FDA-CBER-2022-1614-0710769

US3252020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:19:54

US3252020
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 04:19:54

US3252020

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

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Mar 2021 04:19:54

US3252020
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 04:19:54

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 04:20:31

FDA-CBER-2022-1614-0710774

US3252020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:19

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 06:26:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:17:19

US3252020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:19

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:20:31

US3252020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:19

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	16 Mar 2021 06:26:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:17:19

US3252020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:19

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 04:20:31

US3252020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:19

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	04 Mar 2021 04:20:31

US3252020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:19

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	04 Mar 2021 04:20:31

US3252020
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:10:19
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	04 Mar 2021 04:20:31

US3252020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:19

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:20:31

US3252020
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 11 Aug 2021 22:10:19

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered '1'	System	04 Mar 2021 04:20:31

US3252020

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

Form: Unblinding

Generated On: 11 Aug 2021 22:10:19

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered '1'	System	04 Mar 2021 04:20:31

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:10:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered empty.	System	04 Mar 2021 04:20:42
DataPoint set to visible.	System	04 Mar 2021 04:20:31

US3252020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:10:19
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:10:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered empty.	System	04 Mar 2021 04:20:42
DataPoint set to visible.	System	04 Mar 2021 04:20:31

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 04:21:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 04:21:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 04:20:42
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '11:32' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered '3 Mar 2021 11:32'	System	04 Mar 2021 04:21:40
User entered empty.	System	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '59' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'bpm'	System	04 Mar 2021 04:21:40
User entered empty.	System	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'breaths/min'	System	04 Mar 2021 04:21:40
User entered empty.	System	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'mmHg'	System	04 Mar 2021 04:21:40
User entered empty.	System	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 04:21:40
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'mmHg'	System	04 Mar 2021 04:21:40
User entered empty.	System	04 Mar 2021 04:20:42

US3252020
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:10:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:20:42

US3252020

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:10:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered empty.	System	04 Mar 2021 04:20:42
DataPoint set to visible.	System	04 Mar 2021 04:20:31

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '12:30'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered '3 Mar 2021 12:30'	System	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '99.2' F	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '62'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'bpm'	System	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '14'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'breaths/min'	System	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '124'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'mmHg'	System	04 Mar 2021 04:22:25

US3252020

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '75'	(b) (4), (b) (6)	04 Mar 2021 04:22:25

US3252020
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'mmHg'	System	04 Mar 2021 04:22:25

US3252020

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:10:19

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'No (N)'	(b) (4), (b) (6)	04 Mar 2021 04:22:32

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:22:32

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US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:31:39
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:22:57

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:31:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:22:57

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:31:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 04:22:57

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'mRNA-1273'	System	04 Mar 2021 04:22:57
DataPoint set to visible.	System	04 Mar 2021 04:20:31

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:31:47
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 04:22:57

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:31:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '11:58'	(b) (4), (b) (6)	04 Mar 2021 04:22:57

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered '3 Mar 2021 11:58'	System	04 Mar 2021 04:22:57

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Mar 2021 04:22:57

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:31:53
User entered 'ONCE'	System	04 Mar 2021 04:22:57

US3252020

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

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 04:22:57

US3252020

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:30:07

US3252020

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 04:30:07

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis　(b) (4)	05 Mar 2021 20:07:47
User entered '11:48'	(b) (4), (b) (6)	04 Mar 2021 04:30:07

US3252020

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:10:19

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered '3 Mar 2021 11:48'	System	04 Mar 2021 04:30:07

US3252020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:10:19

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:30:17

US3252020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:10:19

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 11:36:47
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' answered with 'The accession number is 1F63149' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:06:40
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 03MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:27:21
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 04:30:17

US3252020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered '11:48'	(b) (4), (b) (6)	04 Mar 2021 04:30:17

US3252020

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:10:19

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered '3 Mar 2021 11:48'	System	04 Mar 2021 04:30:17

US3252020

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

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:07:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 04:30:22

US3252020
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:45:06
User entered '1'	System	04 Mar 2021 04:30:22

US3252020
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 02:50:56

US3252020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '10 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 02:50:56

US3252020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Mar 2021 02:50:56

US3252020

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 02:50:56

US3252020
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 02:51:00

US3252020
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:12
User entered '1'	System	11 Mar 2021 02:51:00

US3252020

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:46:12
User entered '1'	System	11 Mar 2021 02:51:00
DataPoint set to visible.	System	11 Mar 2021 02:51:00

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓ (b) (4)	05 Apr 2021 19:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6) ▓	01 Apr 2021 02:56:36

FDA-CBER-2022-1614-0710855

US3252020
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓ (b) (4)	05 Apr 2021 19:37:52
User entered '31 Mar 2021'	▓ (b) (4), (b) (6) ▓	01 Apr 2021 02:56:36

US3252020

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Apr 2021 02:56:36

US3252020
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:10:19
Folder OID

Audit	User	Time (GMT)
User entered 'OLD29'	System	01 Apr 2021 02:56:36

US3252020
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:10:19
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Apr 2021 02:57:25

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 02:57:25

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '31 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 02:57:25

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '09:23'	(b) (4), (b) (6)	01 Apr 2021 02:57:25

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '31 Mar 2021 09:23'	System	01 Apr 2021 02:57:25

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '98.0' F	(b) (4), (b) (6)	01 Apr 2021 02:57:25

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Apr 2021 02:57:25

If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 02:57:25

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '69'	(b) (4), (b) (6)	01 Apr 2021 02:57:25

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 02:57:25

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '16'	(b) (4), (b) (6)	01 Apr 2021 02:57:25

FDA-CBER-2022-1614-0710869

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 02:57:25

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ░(b) (4)░	05 Apr 2021 19:37:52
User entered '121'	░(b) (4), (b) (6)░	01 Apr 2021 02:57:25

Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 02:57:25

Diastolic Blood Pressure *(xxx)*

Audit	User		Time (GMT)
User signature succeeded.	Joel Solis	(b) (4)	05 Apr 2021 19:37:52
User entered '74'	(b) (4), (b) (6)		01 Apr 2021 02:57:25

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:10:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 02:57:25

US3252020
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Apr 2021 02:58:14

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 02:58:14

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '31 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 02:58:14

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '10:59'	(b) (4), (b) (6)	01 Apr 2021 02:58:14

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '31 Mar 2021 10:59'	System	01 Apr 2021 02:58:14

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '97.9' F	(b) (4), (b) (6)	01 Apr 2021 02:58:14

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ████ (b) (4)	05 Apr 2021 19:37:52
User entered 'Oral (Oral)'	(b) (4), (b) (6) ████	01 Apr 2021 02:58:14

US3252020
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 02:58:14

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '63'	(b) (4), (b) (6)	01 Apr 2021 02:58:14

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 02:58:14

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '14'	(b) (4), (b) (6)	01 Apr 2021 02:58:14

US3252020
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 02:58:14

US3252020

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:10:19

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '122'	(b) (4), (b) (6)	01 Apr 2021 02:58:14

US3252020
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 02:58:14

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis　(b) (4)	05 Apr 2021 19:37:52
User entered '74'	(b) (4), (b) (6)	01 Apr 2021 02:58:14

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US3252020
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:10:19
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 02:58:14

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▮▮(b) (4)▮▮	05 Apr 2021 19:37:52
User entered 'No (N)'	▮▮(b) (4), (b) (6)▮▮	01 Apr 2021 02:58:34

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▆▆(b) (4)▆	05 Apr 2021 19:37:52
User entered empty.	▆(b) (4), (b) (6)▆	01 Apr 2021 02:58:34

US3252020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

Was study treatment given?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 02:59:06

If No, reason not given

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 02:59:06

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US3252020

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:10:19

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 02:59:06

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	01 Apr 2021 02:59:06
DataPoint set to visible.	System	11 Mar 2021 02:51:00

FDA-CBER-2022-1614-0710896

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '31 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 02:59:06

FDA-CBER-2022-1614-0710897

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered '10:30'	(b) (4), (b) (6)	01 Apr 2021 02:59:06

Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '31 Mar 2021 10:30'	System	01 Apr 2021 02:59:06

Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓(b) (4)▓	05 Apr 2021 19:37:52
User entered 'Left Arm (LEFT ARM)'	▓(b) (4), (b) (6)▓	01 Apr 2021 02:59:06

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US3252020
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:10:19
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Apr 2021 02:59:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Apr 2021 02:59:06

US3252020

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:37:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 02:59:18

US3252020

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:10:19

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 02:59:18

US3252020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:43:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 03:11:29

US3252020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓(b) (4)▓	22 Apr 2021 18:43:37
User entered '7 Apr 2021'	▓(b) (4), (b) (6)▓	08 Apr 2021 03:11:29

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▮(b) (4)▮	22 Apr 2021 18:43:37
User entered 'Contact Made (CONTACT MADE)'	▮(b) (4), (b) (6)▮	08 Apr 2021 03:11:29

US3252020

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:10:19

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:43:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 03:11:29

US3252020
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓▓ (b) (4)	22 Apr 2021 18:43:37
User entered 'Yes (Y)'	(b) (4), (b) (6) ▓▓	08 Apr 2021 03:11:33

US3252020
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:10:19
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 03:11:33

US3252020

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:10:19

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:34
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:09:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 18:35:03
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:22:57

FDA-CBER-2022-1614-0710911

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

AEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▨(b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:00:13
User entered 'USA-US108-2020-mRNA-1273-P301000002'	System	08 Oct 2020 13:00:03
User entered 'New'	(b) (4), (b) (6)	08 Oct 2020 13:00:03

US3252020
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
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)	09 Nov 2020 06:10:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 06:10:26
Data point term sent to Coder	System	09 Nov 2020 05:56:12
User closed query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' (Site from System).	System	09 Nov 2020 05:55:22
Query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' answered with 'Updated.' (Site from System).	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:55:22
Data point term sent to Coder	System	09 Nov 2020 05:55:11
User entered 'COVID-19 infection' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:55:10
Coding entries removed.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:54:56
User entered 'Covid-19' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:54:56
User opened query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' (Site from System).	Coder Import (b) (4) (b) (4)	07 Nov 2020 18:24:38
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)	29 Oct 2020 20:51:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:51:17
Data point term sent to Coder	System	29 Oct 2020 04:23:47
DataPoint Un-verified.	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:23:04

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EAB) (1725)

US3252020
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19
Adverse event

Audit	User	Time (GMT)
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:23:04
User entered 'COVID Positive' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:23:04
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:10:28
User closed query 'PV Query: If this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:34:34
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)	14 Oct 2020 18:20:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:20:37
Query 'PV Query: If this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' answered with 'Term was updated. Thanks. ' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 18:19:56
Data point term sent to Coder	System	14 Oct 2020 18:19:50
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 18:19:43
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 18:19:43
User opened query 'PV Query: If this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 12:14:26
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)	09 Oct 2020 20:58:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:54
Data point term sent to Coder	System	09 Oct 2020 20:47:11
Coding entries removed.	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 20:46:35
User entered 'COVID-19 Positive' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 20:46:35

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 19:48:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 19:48:31
Data point term sent to Coder	System	07 Oct 2020 19:06:53
User entered 'COVID'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:10:43
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:12:35
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:07:33
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:47
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:54:56
User entered '13 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 05:54:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:07:31
User entered '17 Aug 2020'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:46
DataPoint Un-verified.		11 Nov 2020 16:58:44
DataPoint Verified.		27 Oct 2020 19:11:59
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:06:30

US3252020
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:07:49
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

US3252020
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:43:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:27:54
Query 'Per source, end date 27AUG2020. Please review and reconcile. ' canceled (Site from CRA).		15 Apr 2021 16:27:10
User opened query 'Per source, end date 27AUG2020. Please review and reconcile. ' (Site from CRA).		15 Apr 2021 16:27:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 15:41:26
Signature has been broken.		14 Apr 2021 15:41:26
User entered '30 Aug 2020' reason for change: Data Entry Error		14 Apr 2021 15:41:26
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:58:03
User closed query 'Source has AE end date recorded as 22AUG2020. Please review and reconcile with source. ' (Site from CRA).		29 Oct 2020 21:57:55
Query 'Source has AE end date recorded as 22AUG2020. Please review and reconcile with source. ' answered with 'Source reviewed, end date updated.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	28 Oct 2020 14:07:15
User entered '22 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	28 Oct 2020 14:06:59
User opened query 'Source has AE end date recorded as 22AUG2020. Please review and reconcile with source. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:07:14
User closed query 'PV Query: Event end date is reported as 22 Aug 2020; however, the subject had reported COVID-19 symptom of mild runny nose on 29 Aug 2020. Please confirm event end date and updated if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 20:36:37
Query 'PV Query: Event end date is reported as 22 Aug 2020; however, the subject had reported COVID-19 symptom of mild runny nose on 29 Aug 2020. Please confirm event end date and updated if applicable.' answered with 'updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:22:20
User entered '29 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 22:22:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User opened query 'PV Query: Event end date is reported as 22 Aug 2020; however, the subject had reported COVID-19 symptom of mild runny nose on 29 Aug 2020. Please confirm event end date and updated if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 15:04:35
User entered '22 Aug 2020'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 21:58:00
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 19:06:30

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19

Severity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:08:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:08:48
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:08:51
User entered '0'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:08:52
User entered '0'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

US3252020

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:08:54
User entered '0'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:08:56
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:08:58
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:01
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:03
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:04
User entered '0'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓(b) (4)▓	26 Feb 2021 22:28:11
DataPoint Verified.	▓(b) (4), (b) (6)▓	27 Oct 2020 19:09:06
User entered '0'	Nancy Torrence ▓(b) (4)▓ ▓(b) (4)▓	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:08
User entered '0'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:10
User entered 'Not Related (NOT RELATED)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:11
User entered 'Not Related (NOT RELATED)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this is reflected in dosing discontinuation as appropriate. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:56:12
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)	07 Nov 2020 20:55:22
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 'Dosing was discontinued because patient was COVID + which is already documented as an AE. ' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 20:40:41
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	06 Nov 2020 20:08:45
Query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this is reflected in dosing discontinuation as appropriate. Review and update. Else, clarify. ' answered with 'this has been noted in emr system.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 20:06:29
User opened query 'Per DM CLR - RQ: Site's response noted. However, please ensure that this is reflected in dosing discontinuation as appropriate. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:16:14
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:16:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'this was documented through IRT as patient was discontinued from treatment. ' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 13:38:40
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:20:57
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:15
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19

None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:18
User entered '0' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	13 Oct 2020 14:14:04
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Oct 2020 19:08:17
User entered '1' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:08:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Oct 2020 19:06:30
User entered '0'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:49
User entered '1' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	13 Oct 2020 14:14:04
User entered '0'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:51
User entered '0'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:09:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:10:00
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

US3252020
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:10:19
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:10:27
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:35:51
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'RT-PCR swab was added to narrative. Thanks. ' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 18:24:11
User entered 'Symptomatic patient had a COVID nasopharyngeal swab for RT-PCR analysis. Results came back as "Detected".' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 18:23:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 12:14:40
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 19:06:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:10:19

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 19:06:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:34
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:31:48
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:47:37
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:23:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:16:56
User closed query 'Per source, "Z-Pack" please review source and reconcile. ' (Site from CRA).		05 Nov 2020 16:16:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:51:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:51:26
Data point term sent to Coder	System	29 Oct 2020 04:20:43
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:20:32
Query 'Per source, "Z-Pack" please review source and reconcile. ' answered with 'Source has been reviewed and reconciled.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	22 Oct 2020 19:44:35
User opened query 'Per source, "Z-Pack" please review source and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:28:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:47:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:47:22
Data point term sent to Coder	System	13 Oct 2020 14:16:12
Coding entries removed.	Xavier Morales (b) (4) (b) (4)	13 Oct 2020 14:16:05
User entered 'Azithromycin' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	13 Oct 2020 14:16:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 07:37:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 07:37:53
Data point term sent to Coder	System	10 Sep 2020 20:51:46
User entered 'Z pak'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:28:53
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Per ETRTR: Please update AE CRF to indicate ConMeds were dosed for COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:16:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:16:51
DataPoint Un-verified.	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:20:32
User entered 'COVID +' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:20:32
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:28:56
Query 'Per ETRTR: Please update AE CRF to indicate ConMeds were dosed for COVID-19, thanks.' answered with 'has been updated' (Site from CRA).	Xavier Morales (b) (4) (b) (4)	13 Oct 2020 14:14:45
User opened query 'Per ETRTR: Please update AE CRF to indicate ConMeds were dosed for COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 22:05:32
User entered 'COVID'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:40:19
User entered '250'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:40:21
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

FDA-CBER-2022-1614-0710957

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:40:23
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:42:40
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:42:42
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:42:43
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:42:45
User entered empty.	Shannon Moyer (b) (4)	10 Sep 2020 20:51:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:43:17
User entered '17 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:43:20
User entered '0'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'In the electronic source there are two concomitant medication pages. One page is the subject's "Main" source which has an end date of 22AUG2020, however the Convalescent Period source has a conmed page and this medication is listed as ongoing. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:17:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:17:57
Query 'In the electronic source there are two concomitant medication pages. One page is the subject's "Main" source which has an end date of 22AUG2020, however the Convalescent Period source has a conmed page and this medication is listed as ongoing. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 00:56:53
User opened query 'In the electronic source there are two concomitant medication pages. One page is the subject's "Main" source which has an end date of 22AUG2020, however the Convalescent Period source has a conmed page and this medication is listed as ongoing. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:44:05
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 14:16:18
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:18:01
User entered '22 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	11 Sep 2020 14:16:18
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:44:54
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:38:25
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:38:25
User closed query 'Per source in both convalescent and main binders, yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 18:07:31
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 18:07:28
Query 'Per source in both convalescent and main binders, yes. Please review and reconcile. ' answered with 'Reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:08:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:08:02
User opened query 'Per source in both convalescent and main binders, yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:02:19
DataPoint Verified.		11 Nov 2020 17:00:28
User closed query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' (Site from DM).		11 Nov 2020 02:22:06
Query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' answered with 'updated. thanks' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:50:39
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 16:49:53
User entered 'No (N)' reason for change: Data Entry Error		09 Nov 2020 16:49:53
User opened query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' (Site from DM).		06 Nov 2020 14:28:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User closed query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:18:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:18:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:20:32
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:27:31
Query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' answered with 'Source was upadetd' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 00:56:21
User opened query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:04:20
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 20:03:18
DataPoint Verified.		22 Oct 2020 19:44:17
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:02:49
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:02:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 10:32:23
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:51:09

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:51:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 20:51:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:10:19

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 20:51:09

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Concomitant medications are listed in the subject's "main" electronic source, and the "convalescent period" electronic source. The data in both sources does not match (Bromfed in Convalescent Period source, Bromfed DM in the main source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:18:31
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:18:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: BROMFED DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:49:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:49:42
Data point term sent to Coder	System	29 Oct 2020 04:21:44
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:20:58
Query 'Concomitant medications are listed in the subject's "main" electronic source, and the "convalescent period" electronic source. The data in both sources does not match (Bromfed in Convalescent Period source, Bromfed DM in the main source. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 00:59:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Name of Medication

Audit	User	Time (GMT)
User opened query 'Concomitant medications are listed in the subject's "main" electronic source, and the "convalescent period" electronic source. The data in both sources does not match (Bromfed in Convalescent Period source, Bromfed DM in the main source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:48:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: BROMFED DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:07:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:07:26
Data point term sent to Coder	System	09 Oct 2020 13:06:30
Coding entries removed.	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:05:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: BROMFED DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:07:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:07:40
Data point term sent to Coder	System	16 Sep 2020 14:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Name of Medication

Audit	User	Time (GMT)
User closed query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	16 Sep 2020 14:06:43
Query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'name of medication has been updated' (Site from System).	Xavier Morales (b) (4) (b) (4)	16 Sep 2020 14:06:43
User entered 'bromfed dm' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	16 Sep 2020 14:06:17
User opened query 'CDM-Coding: Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4) (b) (4)	15 Sep 2020 09:22:34
Data point term sent to Coder	System	10 Sep 2020 20:53:52
User entered 'Cough Medication'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:48:25
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:18:34
DataPoint Un-verified.	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:20:58
User entered 'COVID +' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:20:58
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:30:31
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:48:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:05:52
User entered 'COVID' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:05:44
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 10:34:00
User entered 'Cough'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Concomitant medications are listed in the subject's "main" electronic source, and the "convalescent period" electronic source. The data in both sources does not match (5ml in Convalescent Period source, 10ml in the main source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:18:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:18:52
Query 'Concomitant medications are listed in the subject's "main" electronic source, and the "convalescent period" electronic source. The data in both sources does not match (5ml in Convalescent Period source, 10ml in the main source. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 00:59:43
User opened query 'Concomitant medications are listed in the subject's "main" electronic source, and the "convalescent period" electronic source. The data in both sources does not match (5ml in Convalescent Period source, 10ml in the main source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:49:21
User entered '10' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	16 Sep 2020 14:06:17
User entered '5'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:10:19
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:49:25
User entered 'mL (mL)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:49:27
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:10:19
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:49:33
User entered 'as needed (PRN)'	Shannon Moyer (b) (4)	10 Sep 2020 20:53:03
	(b) (4)	

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:49:44
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:20:40
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:49:49
User entered empty.	Shannon Moyer (b) (4)	10 Sep 2020 20:53:03
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:49:54
User entered '17 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:50:00
User entered '0'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'Electronic source has 2 concomitant medication pages, one in the main study binder and the other in the convalescent period study binder. In the main study binder there is a stop date of 31AUG, however in the convalescent period binder, the medication is listed as ongoing. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:20:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:20:53
Query 'Electronic source has 2 concomitant medication pages, one in the main study binder and the other in the convalescent period study binder. In the main study binder there is a stop date of 31AUG, however in the convalescent period binder, the medication is listed as ongoing. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 00:59:47
User opened query 'Electronic source has 2 concomitant medication pages, one in the main study binder and the other in the convalescent period study binder. In the main study binder there is a stop date of 31AUG, however in the convalescent period binder, the medication is listed as ongoing. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:51:07
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	16 Sep 2020 14:06:17
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

FDA-CBER-2022-1614-0710987

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:10:19
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:21:09
DataPoint Un-verified.		05 Nov 2020 16:21:07
DataPoint Verified.		05 Nov 2020 16:20:52
User entered '31 Aug 2020' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	16 Sep 2020 14:06:17
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:45:09
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:38:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:38:33
User closed query 'Per source, yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 18:07:56
DataPoint Verified.		21 Nov 2020 18:07:54
Query 'Per source, yes. Please review and reconcile. ' answered with 'Reviewed and updated' (Site from CRA).		12 Nov 2020 22:09:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:09:36
User opened query 'Per source, yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:04:41
User closed query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:22:24
Query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' answered with 'updated. thanks' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:51:26
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 16:51:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 16:51:09
User opened query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:28:49
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:21:11
User closed query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' (Site from CRA).		05 Nov 2020 16:21:05

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Folder: Concomitant Medication and Vaccination (1)

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Generated On: 11 Aug 2021 22:10:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:20:58
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:29:05
Query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 00:59:53
Query 'Was this medication taken for solicited event? is not answered in the subject's convalescent period electronic source. The question is not asked in the subject's "main" electronic source binder. ' canceled (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:04:39
User opened query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:04:30
User opened query 'Was this medication taken for solicited event? is not answered in the subject's convalescent period electronic source. The question is not asked in the subject's "main" electronic source binder. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:52:41
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:03:15
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:03:08
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 10:33:57

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User entered empty.	System	10 Sep 2020 20:53:03

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:10:19

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User entered empty.	System	10 Sep 2020 20:53:03

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:08
User entered empty.	System	10 Sep 2020 20:53:03

FDA-CBER-2022-1614-0710994

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:48:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 02:48:07
Data point term sent to Coder	System	29 Oct 2020 04:21:46
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:21:20
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:55:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:22:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 14:22:19
Data point term sent to Coder	System	09 Oct 2020 13:06:30
Coding entries removed.	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:06:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 20:54:43

Name of Medication

Audit	User	Time (GMT)
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 20:54:43
Data point term sent to Coder	System	10 Sep 2020 20:53:52
User entered 'Aspirin'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:55:37
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:21:49
DataPoint Un-verified.	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:21:20
User entered 'COVID +' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:21:20
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:30:14
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 19:55:44
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:06:09
User entered 'COVID' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:06:02
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 10:36:16
User entered 'Fever'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:21:46
User closed query 'The concomitant medication log exists in the subject's "main" electronic source and their "convalescent period" electronic source. In the main source the dose is 325 mg, in the convalescent period source, the dose is 81 mg. Please review both logs and reconcile. ' (Site from CRA).		05 Nov 2020 16:21:43
Query 'The concomitant medication log exists in the subject's "main" electronic source and their "convalescent period" electronic source. In the main source the dose is 325 mg, in the convalescent period source, the dose is 81 mg. Please review both logs and reconcile. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 01:01:16
User opened query 'The concomitant medication log exists in the subject's "main" electronic source and their "convalescent period" electronic source. In the main source the dose is 325 mg, in the convalescent period source, the dose is 81 mg. Please review both logs and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:01:23
User entered '325'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:25
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:01:28
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query 'The concomitant medication log exists in the subject's "main" electronic source and their "convalescent period" electronic source. In the main source the frequency is "as needed", in the convalescent period source, the frequency is "once daily". Please review both logs and reconcile.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:22:01
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:21:55
Query 'The concomitant medication log exists in the subject's "main" electronic source and their "convalescent period" electronic source. In the main source the frequency is "as needed", in the convalescent period source, the frequency is "once daily". Please review both logs and reconcile.' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 01:01:03
User opened query 'The concomitant medication log exists in the subject's "main" electronic source and their "convalescent period" electronic source. In the main source the frequency is "as needed", in the convalescent period source, the frequency is "once daily". Please review both logs and reconcile.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:02:24
User entered 'as needed (PRN)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

FDA-CBER-2022-1614-0711002

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:02:26
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:02:28
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:02:35
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:02:38
User entered '17 Aug 2020'	Shannon Moyer (b) (4)	10 Sep 2020 20:53:49
	(b) (4)	

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:02:41
User entered '0'	Shannon Moyer (b) (4)	10 Sep 2020 20:53:49
	(b) (4)	

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:26
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:31:26
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Medication reviewed and updated. thanks' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:13:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 14:13:30
User entered 'No (N)' reason for change: Data Entry Error		06 Nov 2020 14:13:30
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).		06 Nov 2020 14:09:44
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:02:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 18:11:13
DataPoint Un-verified.		06 Nov 2020 14:13:30
User entered '22 Aug 2020' reason for change: Data Entry Error		06 Nov 2020 14:13:30
DataPoint Verified.		22 Oct 2020 20:02:49
User entered empty.	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User closed query '"was this medication taken for solicited event?" is yes in the primary binder, but NO in the convalescent binder. Please review and make consistent so this can be verified. ' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 05:47:18
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 05:47:16
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:38:42
Query '"was this medication taken for solicited event?" is yes in the primary binder, but NO in the convalescent binder. Please review and make consistent so this can be verified. ' answered with 'Reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:10:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:10:44
User opened query '"was this medication taken for solicited event?" is yes in the primary binder, but NO in the convalescent binder. Please review and make consistent so this can be verified. ' (Site from CRA).		11 Nov 2020 17:06:40
User closed query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' (Site from CRA).		11 Nov 2020 17:06:40
User closed query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' (Site from DM).		11 Nov 2020 02:22:33
Query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' answered with 'updated. thanks' (Site from DM).		09 Nov 2020 16:52:11
User entered 'No (N)' reason for change: Data Entry Error		09 Nov 2020 16:51:56
User opened query 'Per CDM: Indication is noted as COVID, however COVID is not a solicited event. Kindly review and update else clarify.' (Site from DM).		06 Nov 2020 14:29:25

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US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	29 Oct 2020 04:21:20
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:30:18
Query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' answered with 'updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	27 Oct 2020 01:00:58
User opened query '"Was this medication taken for solicited event?" is not answered in the subject's convalescent period source, and is answered "YES" in the subject's primary source. Please review both logs and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:05:04
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 20:02:55
DataPoint Verified.		22 Oct 2020 20:02:52
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:06:16
User entered 'No (N)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	09 Oct 2020 13:06:02
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary. Please review if condition meets the criteria for Solicited events as outlined in the protocol. Please review entry and update if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 10:36:54
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	10 Sep 2020 20:53:49

PRODUCTION RELEASE (v12.003 EAB) (1725)

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US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User entered empty.	System	10 Sep 2020 20:53:49

US3252020

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:10:19

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User entered empty.	System	10 Sep 2020 20:53:49

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:10:19
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:25:02
User entered empty.	System	10 Sep 2020 20:53:49

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US3252020

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:10:19

Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Aug 2020 07:23:26

US3252020
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:10:19

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:14:20
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:09:10
User closed query 'Per source, subject received COVID+ results on 29-Aug-2020. Therefore, per eCRF Guidelines, date of dosing discontinuation should be 29-Aug-2020. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:09:08
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
Query 'Per source, subject received COVID+ results on 29-Aug-2020. Therefore, per eCRF Guidelines, date of dosing discontinuation should be 29-Aug-2020. Please verify and update EDC accordingly.' answered with 'updated.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 06:20:03
User entered '29 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 06:15:48
User opened query 'Per source, subject received COVID+ results on 29-Aug-2020. Therefore, per eCRF Guidelines, date of dosing discontinuation should be 29-Aug-2020. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 16:33:04
User closed query 'Per eCRF Guidelines, subject received COVID+ results on 29-Aug-2020. Subject was discontinued from dosing as of this date due to positive SARS-COV-2 results. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 16:33:04
Query 'Per eCRF Guidelines, subject received COVID+ results on 29-Aug-2020. Subject was discontinued from dosing as of this date due to positive SARS-COV-2 results. Please verify and update EDC accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 02:30:54
User entered '4 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 02:30:47
User opened query 'Per eCRF Guidelines, subject received COVID+ results on 29-Aug-2020. Subject was discontinued from dosing as of this date due to positive SARS-COV-2 results. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 15:37:48

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3252020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:10:19

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 20:08:45

US3252020

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:10:19

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:14:20
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:37:50
User entered 'Due to SARS-COV-2 (COVID)'	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 20:08:45

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:10:19

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)	27 Apr 2021 10:14:20
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 15:37:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 20:08:45

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'USA-US108-2020-MRNA-1273-P301000002'	System	08 Oct 2020 13:00:03

Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▨(b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711027

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Joel'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Solis'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered '5201 N. 10th Street'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Mcallen'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711031

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'TX'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711032

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'carmpa'	System	08 Oct 2020 13:00:03

Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis　(b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:36:00
User entered 'US'	System	08 Oct 2020 13:01:33

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
E2B Transmit Flag (Derived/Hidden)

Audit	User		Time (GMT)
User signature succeeded.	Joel Solis	(b) (4)	26 Feb 2021 22:28:11
User entered '4'	System		22 Nov 2020 13:17:25
User entered '3'	System		22 Oct 2020 20:37:18
User entered '2'	System		15 Oct 2020 13:36:08
User entered '1'	System		08 Oct 2020 13:01:33

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'USA-US108-2020-MRNA-1273-P301000002'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711038

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711042

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Joel'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Solis'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered '5201 N. 10th Street'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711046

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Mcallen'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711047

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'TX'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711048

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'carmpa'	System	08 Oct 2020 13:00:03

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:36:00
User entered 'US'	System	08 Oct 2020 13:01:33

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
E2B Transmit Flag (Derived/Hidden)

Audit	User		Time (GMT)
User signature succeeded.	Joel Solis	(b) (4)	26 Feb 2021 22:28:11
User entered '4'	System		22 Nov 2020 13:17:25
User entered '3'	System		22 Oct 2020 20:37:18
User entered '2'	System		15 Oct 2020 13:36:08
User entered '1'	System		08 Oct 2020 13:01:33

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
User entered '08/Oct/2020 13:01'	System	08 Oct 2020 13:01:33

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.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:36:00
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 13:01:33

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'USA-US108-2020-MRNA-1273-P301000002'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

US3252020

Folder: SAE USA-US108-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:19

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711061

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Joel'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711062

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Solis'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered '5201 N. 10th Street'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711064

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Mcallen'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'TX'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'carmpa'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:36:00
User entered 'US'	System	08 Oct 2020 13:01:33

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
E2B Transmit Flag (Derived/Hidden)

Audit	User		Time (GMT)
User signature succeeded.	Joel Solis	(b) (4)	26 Feb 2021 22:28:11
User entered '4'	System		22 Nov 2020 13:17:25
User entered '3'	System		22 Oct 2020 20:37:18
User entered '2'	System		15 Oct 2020 13:36:08
User entered '1'	System		08 Oct 2020 13:01:33

FDA-CBER-2022-1614-0711069

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 11 Aug 2021 22:10:19
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
User entered '15/Oct/2020 09:36'	System	15 Oct 2020 13:36:08

US3252020

Folder: SAE USA-US108-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:10:19

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.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 20:36:54
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 13:36:08

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'USA-US108-2020-MRNA-1273-P301000002'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711072

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

US3252020

Folder: SAE USA-US108-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:19

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

US3252020

Folder: SAE USA-US108-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:10:19

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711078

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Joel'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711080

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Solis'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered '5201 N. 10th Street'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Mcallen'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'TX'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'carmpa'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:36:00
User entered 'US'	System	08 Oct 2020 13:01:33

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
E2B Transmit Flag (Derived/Hidden)

Audit	User		Time (GMT)
User signature succeeded.	Joel Solis	(b) (4)	26 Feb 2021 22:28:11
User entered '4'	System		22 Nov 2020 13:17:25
User entered '3'	System		22 Oct 2020 20:37:18
User entered '2'	System		15 Oct 2020 13:36:08
User entered '1'	System		08 Oct 2020 13:01:33

Folder: SAE USA-US108-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:10:19

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
User entered '22/Oct/2020 20:37'	System	22 Oct 2020 20:37:18

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.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 20:37:24
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 20:37:18

Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'USA-US108-2020-MRNA-1273-P301000002'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711092

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'No (N)'	System	08 Oct 2020 13:00:03

FDA-CBER-2022-1614-0711097

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Joel'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Solis'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered '5201 N. 10th Street'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'Mcallen'	System	08 Oct 2020 13:00:03

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'TX'	System	08 Oct 2020 13:00:03

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 13:01:22
User entered 'carmpa'	System	08 Oct 2020 13:00:03

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:20
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:36:00
User entered 'US'	System	08 Oct 2020 13:01:33

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 11 Aug 2021 22:10:19
E2B Transmit Flag (Derived/Hidden)

Audit	User		Time (GMT)
User signature succeeded.	Joel Solis	(b) (4)	26 Feb 2021 22:28:11
User entered '4'	System		22 Nov 2020 13:17:25
User entered '3'	System		22 Oct 2020 20:37:18
User entered '2'	System		15 Oct 2020 13:36:08
User entered '1'	System		08 Oct 2020 13:01:33

US3252020
Folder: SAE USA-US108-2020-MRNA-1273-P301000002
Form: Safety Report Form (4)
Generated On: 11 Aug 2021 22:10:19
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 14:37:14
User entered '22/Nov/2020 08:17'	System	22 Nov 2020 13:17:25

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.	Joel Solis (b) (4)	26 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 14:37:15
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Nov 2020 13:17:25
User entered '0'	(b) (4), (b) (6)	22 Nov 2020 13:17:12

FDA-CBER-2022-1614-0711107