US3252075 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:11:52

All time stamps listed in this document are displayed in GMT

Participant ID	US3252075

mRNA-1273-P301 Completion Guidelines

US3252075

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

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

| Visit date (dd MMM yyyy) | 07 AUG 2020 |

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

| Folder OID | SCRN |

US3252075

Folder: Screening

Form: Demographics

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female ⚪
	Male ⬤
Ethnicity	Hispanic or Latino ⬤
	Not Hispanic or Latino ⚪
	Not Reported ⚪
	Unknown ⚪

Race (Check All That Apply)

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

Folder: Screening
Form: Enrollment
Data signed: (b) (4) 04 Mar 2021 23:20:08
Generated On: 11 Aug 2021 22:11:52

Date of Informed Consent *(dd MMM yyyy)*	7 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

Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

Did the participant meet all eligibility criteria?   Yes ●

                                                            No ◯

Were any significant conditions reported?   Yes ⬤

                                                             No ◯

US3252075

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Condition	RIGHT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN JAN 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3252075

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 04 Mar 2021 23:20:08

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	07 AUG 2020
Time of assessment *(00:00-23:59)*	12:20 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 12:20
Height *(xxx.x)*	65 in
Weight *(xxx.x)*	165.8 lb
BMI *(xxx.x)*	27.64825 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)	

US3252075

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?   Yes ●

                                                           No ◯

Date of examination *(dd MMM yyyy)*   07 AUG 2020

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

US3252075

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 04 Mar 2021 23:20:08

Generated On: 11 Aug 2021 22:11:52

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ◯ No ⬤
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ◯ No ⬤
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ◯ No ⬤
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ⬤ No ◯
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ◯ No ⬤
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ◯ No ⬤
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ◯ No ⬤
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ◯ No ⬤
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ◯ No ⬤
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ◯ No ⬤
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ◯ No ⬤
Other	Yes ◯ No ⬤

Specify _____

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
Resides in Nursing Home or Assisted Living Facility	False

US3252075
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

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

US3252075
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	7 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT1

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

What was the date of randomization? *(dd MMM yyyy)*	07 AUG 2020
What was the participant's randomization number?	185139

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	●

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **04 Mar 2021 23:20:09**

Generated On: 11 Aug 2021 22:11:52

Height	ND - Not Done
Weight	ND - Not Done

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **04 Mar 2021 23:20:09**

Generated On: 11 Aug 2021 22:11:52

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)*	07 AUG 2020
Time of assessment *(00:00-23:59)*	12:20 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 12:20
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **04 Mar 2021 23:20:09**

Generated On: 11 Aug 2021 22:11:52

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)*	07 AUG 2020
Time of assessment *(00:00-23:59)*	14:27 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 14:27
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ⬤
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

US3252075
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

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)*	07 AUG 2020
What was the treatment time? *(00:00-23:59)*	13:37 (24 HR)
Treatment Date and Time (derived)	07 AUG 2020 13:37
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

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?	Yes	⬤
	No	◯

Collection date *(dd MMM yyyy)*	07 AUG 2020
Collection time *(00:00-23:59)*	12:58 (24 HR)
Collection date and time (derived)	07 AUG 2020 12:58

Collection date *(dd MMM yyyy)*			07 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:54	07 AUG 2020 12:54
Nasopharyngeal Swab 2	No		

US3252075
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ◯

Continuing Flag   1

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °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 14:42
PC Open Date & Time	07 AUG 2020 13:57
PC Close Date & Time	07 AUG 2020 16:27

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °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	07 AUG 2020 17:23
PC Open Date & Time	07 AUG 2020 17:22
PC Close Date & Time	08 AUG 2020 11:59

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:11:52

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**	97.9 °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	08 AUG 2020 14:36
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 3

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	98.1 °F

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

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

PC Time Stamp	09 AUG 2020 12:03
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:52

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**	98.6 °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	10 AUG 2020 13:02
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:52

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**	97.6 °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	11 AUG 2020 13:30
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.6 °F

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

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

PC Time Stamp	12 AUG 2020 13:31
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

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**	97.7 °F

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

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

PC Time Stamp	13 AUG 2020 12:00
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

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	07 AUG 2020 14:41
PC Open Date & Time	07 AUG 2020 13:57
PC Close Date & Time	07 AUG 2020 16:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

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	07 AUG 2020 17:24
PC Open Date & Time	07 AUG 2020 17:22
PC Close Date & Time	08 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:52

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	08 AUG 2020 14:37
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:52

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	09 AUG 2020 12:04
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:11:52

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	10 AUG 2020 13:02
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

TIMEPOINT	DAY 5

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

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

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

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

PC Time Stamp	11 AUG 2020 13:30
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	12 AUG 2020 13:32
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:52

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	13 AUG 2020 12:01
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

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

PC Time stamp	07 AUG 2020 14:42
PC Open Date & Time	07 AUG 2020 13:57
PC Close Date & Time	07 AUG 2020 16:27

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:11:52

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	07 AUG 2020 17:25
PC Open Date & Time	07 AUG 2020 17:22
PC Close Date & Time	08 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:52

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	08 AUG 2020 14:38
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 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	09 AUG 2020 12:05
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52

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 ●

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52

	Yes ◯
PC Time stamp	10 AUG 2020 13:03
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

TIMEPOINT	DAY 5

HEADACHE
- None ⬤
- No interference with activity ◯
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
- Any use of prescription pain reliever or prevents daily activity ◯

FATIGUE
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

MUSCLE ACHES ALL OVER BODY
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

JOINT ACHES IN SEVERAL JOINTS
- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

NAUSEA/VOMITING
- None ⬤
- No interference with activity or 1-2 episodes/24 hours ◯
- Some interference with activity or >2 episodes/24 hours ◯
- Prevents daily activity, requires outpatient IV hydration ◯

CHILLS
- None ⬤
- No interference with activity ◯
- Some interference with activity not requiring medical attention ◯
- Prevents daily activity and requires medical attention ◯

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

FDA-CBER-2022-1614-0711157

	Yes ◯
PC Time stamp	11 AUG 2020 13:31
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:11:52

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 ●

	Yes ◯
PC Time stamp	12 AUG 2020 13:33
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:52

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	13 AUG 2020 12:02
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3252075
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

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 _____

US3252075

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                                      No ◯

Continuing Flag   1

US3252075
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

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   THIS PATIENT WAS IN THE
                                              CONVALESCENT PERIOD
If Contact Not Made, please provide Comments   DURING THIS VISIT, SO THIS
                                              SAFETY CALL WAS NOT
                                              EXPECTED.

US3252075

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3252075
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                    No ◯

Continuing Flag   1

US3252075
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **04 Mar 2021 23:21:13**
Generated On: 11 Aug 2021 22:11:52

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	12 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT2

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **04 Mar 2021 23:21:13**

Generated On: 11 Aug 2021 22:11:52

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	12 SEP 2020
Time of assessment *(00:00-23:59)*	13:10 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 13:10
Temperature *(xxx.x)*	98.8 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	89 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Mar 2021 23:21:13

Generated On: 11 Aug 2021 22:11:52

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	

US3252075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **04 Mar 2021 23:21:13**

Generated On: 11 Aug 2021 22:11:52

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?   _____

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? _____

Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **04 Mar 2021 23:21:13**
Generated On: 11 Aug 2021 22:11:52

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	12 SEP 2020
Collection time *(00:00-23:59)*	13:14 (24 HR)
Collection date and time (derived)	12 SEP 2020 13:14

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **04 Mar 2021 23:21:13**

Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*			12 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:21	12 SEP 2020 13:21
Nasopharyngeal Swab 2	No		

US3252075

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:21:13**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3252075
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **04 Mar 2021 23:20:08**
Generated On: 11 Aug 2021 22:11:52

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　 No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　1

US3252075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

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

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

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

Comments

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:20:08**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                   No ○

Continuing Flag   1

US3252075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **04 Mar 2021 23:21:13**

Generated On: 11 Aug 2021 22:11:52

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	10 OCT 2020

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

Folder OID	VISIT3

US3252075
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **04 Mar 2021 23:21:13**
Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	10 OCT 2020
Time of assessment *(00:00-23:59)*	12:57 (24 HR)
Vital Signs Date and Time (derived)	10 OCT 2020 12:57
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Mar 2021 23:21:13

Generated On: 11 Aug 2021 22:11:52

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.

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **04 Mar 2021 23:21:13**

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	10 OCT 2020
Collection time *(00:00-23:59)*	13:21 (24 HR)
Collection date and time (derived)	10 OCT 2020 13:21

US3252075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **04 Mar 2021 23:21:13**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                                         No ○

Continuing Flag   1

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	15 OCT 2020 12:49:16
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	21 OCT 2020 07:49:25
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

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

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 07:34:26
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 18:20:38
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	22 NOV 2020 19:36:39
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 13:57:11
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

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	07 DEC 2020 20:20:48
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 20:04:55
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 20:28:27
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 18:38:58
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	12 JAN 2021 20:33:05
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 20:38:24
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 22:06:14
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

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	31 JAN 2021 00:01:49
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

FDA-CBER-2022-1614-0711209

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	07 FEB 2021 16:08:41
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	15 FEB 2021 12:07:56
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	21 FEB 2021 15:42:48
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	28 FEB 2021 17:23:16
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	07 MAR 2021 13:07:40
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	16 MAR 2021 13:07:45
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 00:01:43
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 19:45:16
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	07 APR 2021 21:18:21
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	11 APR 2021 00:12:52
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	22 APR 2021 09:34:30
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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	27 APR 2021 20:35:57
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 271**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT **DAY 278**

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2021 00:01
Patient Cloud Close Date & Time	13 MAY 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have 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-2022-1614-0711226

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2021 00:01
Patient Cloud Close Date & Time	20 MAY 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT   DAY 292

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2021 00:01
Patient Cloud Close Date & Time	27 MAY 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 299**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2021 00:01
Patient Cloud Close Date & Time	03 JUN 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

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

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have 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-2022-1614-0711234

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 320**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

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

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

FDA-CBER-2022-1614-0711236

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT   DAY 327

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

TIMEPOINT   DAY 334

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

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

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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-2022-1614-0711242

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT <div align="right">DAY 348</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 ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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):

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 AUG 2021 00:01
Patient Cloud Close Date & Time	05 AUG 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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):

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 AUG 2021 00:01
Patient Cloud Close Date & Time	12 AUG 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 383**

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

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

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

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

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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):

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-2022-1614-0711256

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 AUG 2021 00:01
Patient Cloud Close Date & Time	02 SEP 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT   **DAY 397**

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 $\geq$ 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 ⬭

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT DAY 418

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

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

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

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

FDA-CBER-2022-1614-0711264

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

FDA-CBER-2022-1614-0711266

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 OCT 2021 00:01
Patient Cloud Close Date & Time	07 OCT 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 432**

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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):

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 ◯

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT DAY 453

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

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

Fever (Temperature ≥ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 OCT 2021 00:01
Patient Cloud Close Date & Time	04 NOV 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT　　　　　　　　　　　　　　　　　　　　**DAY 474**

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2021 00:01
Patient Cloud Close Date & Time	02 DEC 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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):

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 ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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):

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 ◯

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

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):

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT   **DAY 509**

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

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

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

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

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 516

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

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

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

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

FDA-CBER-2022-1614-0711292

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

FDA-CBER-2022-1614-0711294

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ⃝

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT DAY 537

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT DAY 544

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

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

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

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

FDA-CBER-2022-1614-0711300

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 551**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT <div style="text-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):

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-2022-1614-0711304

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 565**

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 572**

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have 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-2022-1614-0711308

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT   DAY 579

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

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

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

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

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

FDA-CBER-2022-1614-0711316

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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-2022-1614-0711320

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have 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-2022-1614-0711322

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

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 ⬭

FDA-CBER-2022-1614-0711324

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have 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-2022-1614-0711326

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ⦿

FDA-CBER-2022-1614-0711328

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

FDA-CBER-2022-1614-0711332

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

FDA-CBER-2022-1614-0711334

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAY 2022 00:01
Patient Cloud Close Date & Time	02 JUN 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT   DAY 670

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

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

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

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

FDA-CBER-2022-1614-0711336

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 677**

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

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

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

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

FDA-CBER-2022-1614-0711338

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 684**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

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

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

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

FDA-CBER-2022-1614-0711340

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 691**

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

No ◯
Yes ◯

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

No ◯
Yes ◯

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

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

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

No ◯
Yes ◯

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

Fever (Temperature ≥ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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-2022-1614-0711346

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT DAY 719

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

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

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 ◯

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

FDA-CBER-2022-1614-0711352

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 733**

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ⬡

FDA-CBER-2022-1614-0711356

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 747**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

FDA-CBER-2022-1614-0711358

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT   **DAY 754**

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

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT   DAY 761

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

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

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

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

FDA-CBER-2022-1614-0711362

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

FDA-CBER-2022-1614-0711364

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 ◯

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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-2022-1614-0711370

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT	**DAY 796**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3252075

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:11:52

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		27 FEB 2021 21:07:02

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **05 Mar 2021 20:10:31**

Generated On: 11 Aug 2021 22:11:52

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 11 NOV 2020 |

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

Comments   PATIENT DID NOT ANSWER
                                            PHONE CALL, TEXT OR EMAIL.

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:10:31**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                          No ○

Continuing Flag   1

US3252075
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 20:10:31**
Generated On: 11 Aug 2021 22:11:52

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 11 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

US3252075
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 20:10:31**
Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3252075
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **05 Mar 2021 20:10:31**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ◯

Continuing Flag   1

US3252075
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **22 Apr 2021 18:45:32**
Generated On: 11 Aug 2021 22:11:52

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 14 APR 2021 |

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

| Comments | PATIENT MISSED SAFETY CALL |

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

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 Apr 2021 19:41:15**
Generated On: 11 Aug 2021 22:11:52

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	9 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT4

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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) _____

US3252075

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

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.

US3252075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	9 MAR 2021
Collection time *(00:00-23:59)*	10:55 (24 HR)
Collection date and time (derived)	9 MAR 2021 10:55

US3252075

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?　　　　　　　　　　Yes ●

No ○

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3252075
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?	Yes ◯
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)* _____

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

Comments

If Contact Not Made, please provide Comments _____

Is the participant continuing to the next visit?   Yes ◯

No ◯

Continuing Flag   _____

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID-19 Contact
Data signed: (b) (4) **05 Mar 2021 20:10:28**
Generated On: 11 Aug 2021 22:11:52

Date of Contact	13 AUG 2020
Time of Contact	16:59
Date and Time of Contact (derived)	13 AUG 2020 16:59
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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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	99 %
O2 Saturation Units	%
Temperature	97.9 F

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

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

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

Difficulty Breathing	
	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

FDA-CBER-2022-1614-0711392

Not Done ◯

Fatigue

None ◯

Mild ⬤

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ⬤

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ◯
Mild ●
Moderate ◯
Severe ◯
Not Done ◯

Runny Nose (Rhinorrhea)

None ◯
Mild ●
Moderate ◯
Severe ◯
Not Done ◯

Nausea

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Vomiting

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Diarrhea

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Sore Throat

None ●
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

FDA-CBER-2022-1614-0711394

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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	◯

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	15 AUG 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	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 ◯

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

	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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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 ○

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 11:33:44

Generated On: 11 Aug 2021 22:11:52

	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	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 ◯

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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-2022-1614-0711403

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

	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	97 %
O2 Saturation Units	%
Temperature	96.9 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

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

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

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

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

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

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

Nasal Congestion

None ○
Mild ●
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ○
Mild ●
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

	Day 33 ○
	Day 34 ○
	Day 35 ○
	Day 36 ○
	Day 37 ○
	Day 38 ○
	Day 39 ○
	Day 40 ○
Date	17 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.9 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 ◯

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

	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	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 ⬭

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

	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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

Symptom Day

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

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	19 AUG 2020
Assessment Not Done	False
O2 Saturation	97 %
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 ◯

Nasal Congestion

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

Runny Nose (Rhinorrhea)

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

Nausea

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

Vomiting

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

Diarrhea

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

Sore Throat

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

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	20 AUG 2020
Assessment Not Done	False
O2 Saturation	99 %
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 ◯

Not Done ◯

Fatigue

None ◯
Mild ⬤
Moderate ◯
Severe ◯
Not Done ◯

Muscle Aches (Myalgia)

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Body Aches

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Headache

None ◯
Mild ⬤
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Taste

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

New Loss of Smell

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

FDA-CBER-2022-1614-0711421

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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	21 AUG 2020
Assessment Not Done	False
O2 Saturation	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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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	◯

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

	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	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 ◯

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

Not Done ◯

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

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

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

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

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

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

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	23 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 ◯

FDA-CBER-2022-1614-0711432

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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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	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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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	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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Data signed: (b) (4) 28 Apr 2021 11:33:44
Generated On: 11 Aug 2021 22:11:52

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	◯

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

	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	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 ⬭

PRODUCTION RELEASE (v12.003 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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (15)
Data signed: (b) (4) 28 Apr 2021 11:33:44
Generated On: 11 Aug 2021 22:11:52

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 ◯

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

	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	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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

Symptom Day

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

	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	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 ◯

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

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	◯

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) **28 Apr 2021 11:33:44**

Generated On: 11 Aug 2021 22:11:52

	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	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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

Symptom Day

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	30 AUG 2020
Assessment Not Done	False
O2 Saturation	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 ◯

FDA-CBER-2022-1614-0711460

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	◯

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Data signed: (b) (4) **28 Apr 2021 11:33:44**
Generated On: 11 Aug 2021 22:11:52

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	31 AUG 2020
Assessment Not Done	False
O2 Saturation	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 ○

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **05 Mar 2021 20:10:28**
Generated On: 11 Aug 2021 22:11:52

Date of Visit	13 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	13 AUG 2020
Type of Test Performed	Nasopharyngeal Swab ⬤
	Nasal Swab ◯
	Saliva Test ◯
	Other ◯
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ◯
	No ⬤
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ◯
	No ◯
COVID-19 Positive (CSA Programming Field Only)	1

Did the subject have Respiratory Rates ≥ 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 at sea level?   Yes ◯   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	

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 _____

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **05 Mar 2021 20:10:29**
Generated On: 11 Aug 2021 22:11:52

Generate Next COVID-19 Assessment   Yes ◯

                                                                      No ⬤

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 AUG 2020
Day 5	Yes	17 AUG 2020
Day 7	Yes	19 AUG 2020
Day 9	Yes	21 AUG 2020
Day 14	Yes	26 AUG 2020
Day 21	Yes	02 SEP 2020
Day 28	No	

US3252075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:10:30

Generated On: 11 Aug 2021 22:11:52

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SICKD1

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 20:10:30

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	13 AUG 2020
Time of assessment *(00:00-23:59)*	16:50 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 16:50
Height *(xxx.x)*	65 in
Weight *(xxx.x)*	165.0 lb
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252075

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?   Yes ⬤

     No ◯

Date of examination *(dd MMM yyyy)*   13 AUG 2020

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

US3252075

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

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

Date of Collection	13 AUG 2020

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

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

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) 05 Mar 2021 20:10:28
Generated On: 11 Aug 2021 22:11:52

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)	_____

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

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.

US3252075

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

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

Yes ◯

No ⬤

NA (COVID-19 Negative) ◯

Date of Collection

US3252075

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

Form: Visit Date

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

Was this visit performed?	Yes ●
	No ◯

Visit date (dd MMM yyyy)	9 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ●

Folder OID	UNBLND_DECIDE

Date of updated informed consent *(dd MMM yyyy)*	9 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)*	9 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	
Continuing with mRNA-1273	1

US3252075

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

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

US3252075

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	9 MAR 2021
Time of assessment *(00:00-23:59)*	10:55 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 10:55
Temperature *(xxx.x)*	98.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3252075

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ⭕
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⭕
Date of assessment *(dd MMM yyyy)*	9 MAR 2021
Time of assessment *(00:00-23:59)*	11:46 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 11:46
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ⬤
	Axillary ⭕
	Other ⭕
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

US3252075

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

Form: Physical Examination

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

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.

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) 05 Apr 2021 19:41:15
Generated On: 11 Aug 2021 22:11:52

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)*	9 MAR 2021
What was the treatment time? *(00:00-23:59)*	11:13 (24 HR)
Treatment Date and Time (derived)	9 MAR 2021 11:13
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

US3252075

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	9 MAR 2021
Collection time *(00:00-23:59)*	10:57 (24 HR)
Collection date and time (derived)	9 MAR 2021 10:57

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	9 MAR 2021
Collection time *(00:00 - 23:59)*	10:57
Collection Date and Time (derived)	9 MAR 2021 10:57

US3252075

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

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3252075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

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

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

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

Comments

If Contact Not Made, please provide Comments

US3252075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **05 Apr 2021 19:41:15**

Generated On: 11 Aug 2021 22:11:52

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

Continuing Flag	1
OLD29 Placebo Flag	1

US3252075
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **22 Apr 2021 18:45:32**
Generated On: 11 Aug 2021 22:11:52

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	9 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD29

US3252075

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) **22 Apr 2021 18:45:32**

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?	Yes ⬤
	No ⭕
Date of assessment *(dd MMM yyyy)*	9 APR 2021
Time of assessment *(00:00-23:59)*	07:26 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 07:26
Temperature *(xxx.x)*	98.1 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)*	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252075

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **22 Apr 2021 18:45:32**

Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?   Yes ●

                                                            No ○

Date of examination *(dd MMM yyyy)*   9 APR 2021

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

US3252075

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **22 Apr 2021 18:45:32**

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	9 APR 2021
Collection time *(00:00-23:59)*	09:45 (24 HR)
Collection date and time (derived)	9 APR 2021 09:45

US3252075

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

Did the participant experience any adverse events?   Yes ●

          No ◯

If Yes, enter details on the Adverse Events form.

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

AEID	USA-US108-2020-MRNA-1273-P30 1000001
Adverse event	COVID-19
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ●
	No ○
Start date *(dd MMM yyyy)*	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)*	21 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 ○

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

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

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

	SAW PATIENT TODAY AND PATIENT IS SYMPTOMATIC WILL START A BABY ASPIRIN 81 MG QD, ZPAK TAKE AS DIRECTED, CLARITIN 10 MG QD AND TYLENOL 325MG Q4 QD FEVER AND PAIN. PATIENT WITH ELEVATED BLOOD PRESSURE X2, WITH NO DIAGNOSIS OF HYPERTENSION. I RECOMMEND A LOW SALT DIET AND MONITORING OF BLOOD PRESSURE AND TO FOLLOW UP WITH PMD.
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

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

No ◯

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

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

Name of Medication	BABY ASPIRIN

Prophylaxis	
	Yes ◯
	No ⬤

Indication	COVID POSITIVE
Dose per administration	81

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	13 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	19 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 ⬤

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

Name of Medication	ZPACK

Prophylaxis

Yes ⚪

No ⚫

Indication	COVID POSITIVE
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)*	13 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	13 AUG 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	CLARITIN

Prophylaxis	Yes ◯
	No ⬤

Indication	COVID POSITIVE
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 ◯

	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)*	13 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	19 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 ●

FDA-CBER-2022-1614-0711507

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

Name of Medication	TYLENOL
Prophylaxis	Yes ◯
	No ⬤
Indication	COVID POSITIVE
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 ◯

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)*	13 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 AUG 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

Name of Medication	ZPACK
Prophylaxis	Yes ⬭
	No ⬤
Indication	COVID POSITIVE
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 ⬭

	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)*	14 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	19 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 ⬤

US3252075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **05 Mar 2021 20:10:28**

Generated On: 11 Aug 2021 22:11:52

Were any concomitant procedures performed?   Yes ◯

                                                                                    No ⬤

If yes, please complete Concomitant Procedures form.

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify

Date of dosing discontinuation (dd MMM yyyy)	19 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 ◯

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form (1)
Data signed: (b) (4) **05 Mar 2021 20:10:30**
Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	25/AUG/2020 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/SEP/2020 09:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Data signed: (b) (4) **05 Mar 2021 20:10:30**
Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	04/NOV/2020 15:59
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

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/NOV/2020 17:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form (5)
Data signed: (b) (4) **05 Mar 2021 20:10:30**
Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/NOV/2020 18:24
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

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	22/NOV/2020 08:57
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

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form (7)
Data signed: (b) (4) **05 Mar 2021 20:10:30**
Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	24/NOV/2020 10:37
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

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	01/DEC/2020 19:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) **05 Mar 2021 20:10:30**

Generated On: 11 Aug 2021 22:11:52

SAEID	USA-US108-2020-MRNA-1273-P30 1000001
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	78504
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/DEC/2020 07:28
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

US3252075 (Prod: Centex Studies Inc)

US3252075

Form: Participant Creation

Generated On: 11 Aug 2021 22:11:52

Participant ID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 02:04:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'US3252075'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:08

US3252075

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:51:31
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:25

US3252075

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:16
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:09

US3252075
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:16
User entered 'Clinic (Clinic)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:25

US3252075
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'SCRN'	System	07 Aug 2020 18:40:25

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:49
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:10

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:53
User entered '67'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'YEARS'	System	07 Aug 2020 18:40:47

US3252075
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:11:52

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered '67'	System	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:53:54
User entered 'Male (M)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:11:52
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Xavier Morales (b) (4)	07 Aug 2020 18:40:47

US3252075
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:11:52
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '1'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4)	07 Aug 2020 18:40:47
	(b) (4)	

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:11:52
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:11:52
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:11:52

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:00
User entered '0'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:47

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:21
User entered '7 Aug 2020'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'Aug 2020'	System	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered '2020'	System	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:22
User entered 'Amendment 1 (1)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:24
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:25
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:27
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 01:39:10
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:40:58

US3252075

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:11:52

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 01:39:10
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:09

US3252075
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:11:52
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered '1'	System	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:11:52

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:54:56
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:11:52

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:04
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:38:30

US3252075
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:11:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'PER PATIENT NO MEDICATION TAKEN FOR TYPE 2 DIABETES .' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	26 Sep 2020 01:54:06
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:04:43
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 17:39:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 17:39:49
Data point term sent to Coder	System	08 Aug 2020 17:39:12
User entered 'TYPE 2 DIABETES'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'UN UNK 2019'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'Jan 2019'	System	08 Aug 2020 17:39:02

US3252075
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:11:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered '2019'	System	08 Aug 2020 17:39:02

US3252075

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:11:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered empty.	System	08 Aug 2020 17:39:02

US3252075
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:11:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered empty.	System	08 Aug 2020 17:39:02

US3252075
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:11:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:33:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:56:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:56:37
Data point term sent to Coder	System	21 Oct 2020 17:55:52
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'PATIENT COULD NOT RECALL IF HE HAD ANY DIAGNOSIS ASSOCIATED WITH RIGHT HIP REPLACEMENT . ' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	26 Sep 2020 01:53:00
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:05:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 20:51:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Aug 2020 20:51:38
Data point term sent to Coder	System	23 Aug 2020 20:51:02
User entered 'Right Hip Replacement'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis　(b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'UN Jan 2016'	Joanna Gurrola Mahoney　(b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered '0'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered 'UN Jan 2016'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:55:52
User entered '0'	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'Jan 2016'	System	23 Aug 2020 20:50:17

US3252075
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:11:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered '2016'	System	23 Aug 2020 20:50:17

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:11:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'Jan 2016'	System	23 Aug 2020 20:50:17

US3252075
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:11:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered '2016'	System	23 Aug 2020 20:50:17

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:37
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:39
User entered '07 Aug 2020'	Shannon Moyer (b) (4)	08 Aug 2020 17:40:10
	(b) (4)	

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:41
User entered '12:20'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered '07 Aug 2020 12:20'	System	08 Aug 2020 17:40:10

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:45
User entered '65' in	Shannon Moyer (b) (4)	08 Aug 2020 17:40:10
DataPoint set to visible.	(b) (4) System	07 Aug 2020 18:41:02

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:50
User entered '165.8' lb	Shannon Moyer (b) (4)	08 Aug 2020 17:40:10
DataPoint set to visible.	(b) (4) System	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
Amendment Manager: User entered '27.64825'	System	16 Sep 2020 23:47:38
User entered '27.6'	System	08 Aug 2020 17:40:10
DataPoint set to visible.	System	07 Aug 2020 18:41:02

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'kg/m2'	System	08 Aug 2020 17:40:10
DataPoint set to visible.	System	07 Aug 2020 18:41:02

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:51:54
User entered '98.7' F	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:51:54
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:51:54
User entered '80'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'bpm'	System	08 Aug 2020 17:40:10

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:51:54
User entered '16'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'breaths/min'	System	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:51:54
User entered '145'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'mmHg'	System	08 Aug 2020 17:40:10

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:56:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:51:54
User entered '90'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:10

US3252075
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User entered 'mmHg'	System	08 Aug 2020 17:40:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12

US3252075

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12

US3252075
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:24
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:25

US3252075

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:24
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	23 Sep 2020 17:04:19
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 02:27:41
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 12:50:48
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 16:46:49
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:40:25

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:03:51
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:41:08
	(b) (4)	

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '1'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4)	08 Aug 2020 17:41:08
	(b) (4)	

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

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 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:11:52
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '0'	Shannon Moyer (b) (4)	08 Aug 2020 17:41:08
	(b) (4)	

US3252075

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:11:52

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:17:12
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:06
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:41:08

US3252075
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:16
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:17

FDA-CBER-2022-1614-0711623

US3252075

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:16
User entered '7 Aug 2020'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:17

US3252075
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:16
User entered 'Clinic (Clinic)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:17

US3252075
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'VISIT1'	System	07 Aug 2020 18:41:17

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:26
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:10

US3252075
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:11:52

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:35
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:54:48
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:54:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 17:59:10
User entered '185139' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:10

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:52

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:38
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:59:10

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:52

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)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:48
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:52

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)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:48
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:48
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:52

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:48
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:11:52

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:08:48
User entered 'No (N)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:41:34

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:52:51
User entered '65' in (b) (4)	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:11:52
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:52:51
User entered '165.1' lb	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:11:52
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:52:51
User entered '65' in (b) (4)	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18

US3252075
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:11:52
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:52:51
User entered '165.1' lb	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:11:52
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:20
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:22
User entered '12:20'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered '07 Aug 2020 12:20'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:25
User entered '98.1' F	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:26
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:30
User entered empty.	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18
	(b) (4)	

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:32
User entered '80'	Shannon Moyer (b) (4)	08 Aug 2020 17:42:18
	(b) (4)	

US3252075
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'bpm'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:34
User entered '16'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'breaths/min'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:36
User entered '145'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'mmHg'	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:38
User entered '90'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'mmHg'	System	08 Aug 2020 17:42:18

US3252075
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:11:52
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:52:51
User entered '65' in	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:57:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:52:51
User entered '165.1' lb	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:26:53
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:43:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 20:43:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 17:42:18
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:26:55
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '07 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:26:57
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:54:43
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)	20 Aug 2020 20:44:08
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	20 Aug 2020 20:43:55
User entered '14:27' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered '07 Aug 2020 14:27'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:26:59
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '98.3' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:27:01
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:11:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:27:03
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:27:04
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '81' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'bpm'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:27:06
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '16' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'breaths/min'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:27:08
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '146' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'mmHg'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:27:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '83' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 20:43:55
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:18

US3252075

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'mmHg'	System	20 Aug 2020 20:43:55
User entered empty.	System	08 Aug 2020 17:42:18

US3252075
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:11:52
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:09:06
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:47:58
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:30

FDA-CBER-2022-1614-0711673

US3252075
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:11:52
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:09:08
User entered empty; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:47:58
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:42:30

US3252075
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:11:52
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:09:31
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

US3252075
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:11:52
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:09:34
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:03
User entered empty.	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:44:52
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 20:47:28
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 22:01:43
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 22:01:34
User entered '07 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	06 Nov 2020 22:01:34
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 21:10:11
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:06
User entered '7 Aug 2020'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
Query 'Per CDM: Please note this field is not required, unless start time is within 24 hours of dosing time (07-AUG-2020; 13:37hrs)?. Please review and amend accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:42:53
User opened query 'Per CDM: Please note this field is not required, unless start time is within 24 hours of dosing time (07-AUG-2020; 13:37hrs)?. Please review and amend accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:41:50
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:09
User entered '13:37'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

US3252075
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:11:52

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered '07 Aug 2020 13:37'	System	06 Nov 2020 22:01:34
User entered '7 Aug 2020 13:37'	System	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:17
User entered 'Left Arm (LEFT ARM)'	Xavier Morales (b) (4) (b) (4)	07 Aug 2020 18:42:05

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:11:52
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:21
User entered 'ONCE'	System	07 Aug 2020 18:42:05

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:11:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 18:42:05

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:31
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:07

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:31
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:07

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:10:31
User entered '12:58'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:07

US3252075

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered '07 Aug 2020 12:58'	System	08 Aug 2020 17:43:07

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis　(b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	08 Aug 2020 17:43:29
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered '12:54'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered '07 Aug 2020 12:54'	System	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

US3252075

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:11:06
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered empty.	System	08 Aug 2020 17:43:29

FDA-CBER-2022-1614-0711697

US3252075

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User closed query 'Per CDM: Is the participant continuing to the next visit? (V2 Day 29) = No however, Visit 2 eCRF forms have been completed? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:47:42
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:46:58
User closed query '"Is the participant continuing to the next visit?" is not complete in source, and thus, unable to be verified. Please review and reconcile.' (Site from CRA).		08 Nov 2020 20:45:38
Query 'Per CDM: Is the participant continuing to the next visit? (V2 Day 29) = No however, Visit 2 eCRF forms have been completed? Please review and update accordingly.' answered with 'Updated and captured in source' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 14:32:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	06 Nov 2020 14:32:23
User opened query 'Per CDM: Is the participant continuing to the next visit? (V2 Day 29) = No however, Visit 2 eCRF forms have been completed? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:55:59
Query '"Is the participant continuing to the next visit?" is not complete in source, and thus, unable to be verified. Please review and reconcile.' answered with 'Reviewed and reconciled as "no".' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 20:39:32
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 20:39:04
User opened query '"Is the participant continuing to the next visit?" is not complete in source, and thus, unable to be verified. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:12:09
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:36

US3252075

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:08:09
User entered '1'	System	06 Nov 2020 14:32:23
User entered empty.	System	21 Oct 2020 20:39:04
User entered '1'	System	08 Aug 2020 17:43:36

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '488271d7-2196-49a4-aa3d-81019e9f40c0'	System	07 Aug 2020 19:42:15
User entered 'Yes (Y)'	System	07 Aug 2020 19:42:15

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:11:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:59', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '488271d7-2196-49a4-aa3d-81019e9f40c0'	System	07 Aug 2020 19:42:15
User entered '98.3'	System	07 Aug 2020 19:42:15

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:06', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '488271d7-2196-49a4-aa3d-81019e9f40c0'	System	07 Aug 2020 19:42:15
User entered 'No (N)'	System	07 Aug 2020 19:42:15

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:12', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '488271d7-2196-49a4-aa3d-81019e9f40c0'	System	07 Aug 2020 19:42:15
User entered '07 Aug 2020 14:42'	System	07 Aug 2020 19:42:15

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 13:57'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 16:27'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:22:46', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3151d1e-52ae-4056-800a-e32f6644c61d'	System	07 Aug 2020 22:23:35
User entered 'Yes (Y)'	System	07 Aug 2020 22:23:35

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:11:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:22:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3151d1e-52ae-4056-800a-e32f6644c61d'	System	07 Aug 2020 22:23:35
User entered '97.5'	System	07 Aug 2020 22:23:35

FDA-CBER-2022-1614-0711709

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:23:03', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3151d1e-52ae-4056-800a-e32f6644c61d'	System	07 Aug 2020 22:23:35
User entered 'No (N)'	System	07 Aug 2020 22:23:35

FDA-CBER-2022-1614-0711710

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:23:29', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3151d1e-52ae-4056-800a-e32f6644c61d'	System	07 Aug 2020 22:23:35
User entered '07 Aug 2020 17:23'	System	07 Aug 2020 22:23:35

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 17:22'	System	07 Aug 2020 18:42:05

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 2'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:11:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:36:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '07523a48-bb0a-4ab2-bec6-922a38284064'	System	08 Aug 2020 19:36:57
User entered 'Yes (Y)'	System	08 Aug 2020 19:36:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:36:36', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '07523a48-bb0a-4ab2-bec6-922a38284064'	System	08 Aug 2020 19:36:57
User entered '97.9'	System	08 Aug 2020 19:36:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:36:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '07523a48-bb0a-4ab2-bec6-922a38284064'	System	08 Aug 2020 19:36:57
User entered 'No (N)'	System	08 Aug 2020 19:36:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:36:51', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '07523a48-bb0a-4ab2-bec6-922a38284064'	System	08 Aug 2020 19:36:57
User entered '08 Aug 2020 14:36'	System	08 Aug 2020 19:36:57

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 3'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:03:22', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'ee55d411-951e-4117-a15d-ff7bccada20c'	System	09 Aug 2020 17:03:53
User entered 'Yes (Y)'	System	09 Aug 2020 17:03:53

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:03:37', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'ee55d411-951e-4117-a15d-ff7bccada20c'	System	09 Aug 2020 17:03:53
User entered '98.1'	System	09 Aug 2020 17:03:53

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:03:42', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'ee55d411-951e-4117-a15d-ff7bccada20c'	System	09 Aug 2020 17:03:53
User entered 'No (N)'	System	09 Aug 2020 17:03:53

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) System	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:03:50', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'ee55d411-951e-4117-a15d-ff7bccada20c'	System	09 Aug 2020 17:03:53
User entered '09 Aug 2020 12:03'	System	09 Aug 2020 17:03:53

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 4'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:11:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:01:50', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3d24317-0b5e-432f-bc59-f456231cc823'	System	10 Aug 2020 18:02:20
User entered 'Yes (Y)'	System	10 Aug 2020 18:02:20

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:11:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3d24317-0b5e-432f-bc59-f456231cc823'	System	10 Aug 2020 18:02:20
User entered '98.6'	System	10 Aug 2020 18:02:20

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:11', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3d24317-0b5e-432f-bc59-f456231cc823'	System	10 Aug 2020 18:02:20
User entered 'No (N)'	System	10 Aug 2020 18:02:20

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a3d24317-0b5e-432f-bc59-f456231cc823'	System	10 Aug 2020 18:02:20
User entered '10 Aug 2020 13:02'	System	10 Aug 2020 18:02:20

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 5'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:11:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:29:44', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c5b78e1-b257-410e-8207-5c40cf3cf64f'	System	11 Aug 2020 18:30:06
User entered 'Yes (Y)'	System	11 Aug 2020 18:30:06

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:29:52', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c5b78e1-b257-410e-8207-5c40cf3cf64f'	System	11 Aug 2020 18:30:06
User entered '97.6'	System	11 Aug 2020 18:30:06

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:29:56', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c5b78e1-b257-410e-8207-5c40cf3cf64f'	System	11 Aug 2020 18:30:06
User entered 'No (N)'	System	11 Aug 2020 18:30:06

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c5b78e1-b257-410e-8207-5c40cf3cf64f'	System	11 Aug 2020 18:30:06
User entered '11 Aug 2020 13:30'	System	11 Aug 2020 18:30:06

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:11:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 6'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:16', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '722ab52f-7393-4153-94d9-99db0c87ed3e'	System	12 Aug 2020 18:31:42
User entered 'Yes (Y)'	System	12 Aug 2020 18:31:42

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '722ab52f-7393-4153-94d9-99db0c87ed3e'	System	12 Aug 2020 18:31:42
User entered '97.6'	System	12 Aug 2020 18:31:42

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:29', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '722ab52f-7393-4153-94d9-99db0c87ed3e'	System	12 Aug 2020 18:31:42
User entered 'No (N)'	System	12 Aug 2020 18:31:42

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:39', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '722ab52f-7393-4153-94d9-99db0c87ed3e'	System	12 Aug 2020 18:31:42
User entered '12 Aug 2020 13:31'	System	12 Aug 2020 18:31:42

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 7'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:11:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:00:30', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '588670f7-c7f3-4f63-a8fc-b3071109d4f4'	System	13 Aug 2020 17:00:57
User entered 'Yes (Y)'	System	13 Aug 2020 17:00:57

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:11:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:00:36', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '588670f7-c7f3-4f63-a8fc-b3071109d4f4'	System	13 Aug 2020 17:00:57
User entered '97.7'	System	13 Aug 2020 17:00:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:00:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '588670f7-c7f3-4f63-a8fc-b3071109d4f4'	System	13 Aug 2020 17:00:57
User entered 'No (N)'	System	13 Aug 2020 17:00:57

US3252075
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:00:54', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '588670f7-c7f3-4f63-a8fc-b3071109d4f4'	System	13 Aug 2020 17:00:57
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 17:00:57

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:40:59', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered 'None (1)'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered 'No (N)'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:08', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered 'No (N)'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered 'None (1)'	System	07 Aug 2020 19:41:26

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:41:21', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '62a97744-8cf0-4ad8-b389-889f29b4a87b'	System	07 Aug 2020 19:41:26
User entered '07 Aug 2020 14:41'	System	07 Aug 2020 19:41:26

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 13:57'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 16:27'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:23:55', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:01', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered 'No (N)'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:06', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered 'No (N)'	System	07 Aug 2020 22:24:40

FDA-CBER-2022-1614-0711767

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:21', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered 'None (1)'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:36', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '1db8ea7b-03b2-462d-9960-56a1c053b32c'	System	07 Aug 2020 22:24:40
User entered '07 Aug 2020 17:24'	System	07 Aug 2020 22:24:40

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 17:22'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 2'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:01', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 19:37:42

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:11:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:09', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered 'No (N)'	System	08 Aug 2020 19:37:42

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:14', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered 'No (N)'	System	08 Aug 2020 19:37:42

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:26', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered 'None (1)'	System	08 Aug 2020 19:37:42

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:39', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '73294901-c9c7-4203-b875-0fc8705e1eff'	System	08 Aug 2020 19:37:42
User entered '08 Aug 2020 14:37'	System	08 Aug 2020 19:37:42

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:11:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 3'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 17:04:27

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered 'No (N)'	System	09 Aug 2020 17:04:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:10', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered 'No (N)'	System	09 Aug 2020 17:04:27

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered 'None (1)'	System	09 Aug 2020 17:04:27

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:11:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '2857ba1c-4531-4edf-bc2f-b64824b6a2c7'	System	09 Aug 2020 17:04:27
User entered '09 Aug 2020 12:04'	System	09 Aug 2020 17:04:27

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 4'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:27', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 18:02:54

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:33', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered 'No (N)'	System	10 Aug 2020 18:02:54

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:40', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered 'No (N)'	System	10 Aug 2020 18:02:54

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:46', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered 'None (1)'	System	10 Aug 2020 18:02:54

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:52', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c307f2d4-a8bc-4c91-b2e6-9b6a583bafd5'	System	10 Aug 2020 18:02:54
User entered '10 Aug 2020 13:02'	System	10 Aug 2020 18:02:54

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:11:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 5'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:19', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered 'None (1)'	System	11 Aug 2020 18:30:47

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered 'No (N)'	System	11 Aug 2020 18:30:47

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:30', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered 'No (N)'	System	11 Aug 2020 18:30:47

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:37', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered 'None (1)'	System	11 Aug 2020 18:30:47

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '77f9a3a0-36d8-4ef8-9ec8-f695e1433403'	System	11 Aug 2020 18:30:47
User entered '11 Aug 2020 13:30'	System	11 Aug 2020 18:30:47

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 6'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:49', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered 'None (1)'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:31:58', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered 'No (N)'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered 'No (N)'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered 'None (1)'	System	12 Aug 2020 18:32:21

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:11:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:19', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '42a25494-6fc6-431e-a49b-3188f4a0a795'	System	12 Aug 2020 18:32:21
User entered '12 Aug 2020 13:32'	System	12 Aug 2020 18:32:21

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:11:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 7'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered 'None (1)'	System	13 Aug 2020 17:01:29

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered 'No (N)'	System	13 Aug 2020 17:01:29

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered 'No (N)'	System	13 Aug 2020 17:01:29

US3252075

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:20', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered 'None (1)'	System	13 Aug 2020 17:01:29

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:11:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:27', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '211af047-89d5-4b42-94b9-135c2e135155'	System	13 Aug 2020 17:01:29
User entered '13 Aug 2020 12:01'	System	13 Aug 2020 17:01:29

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:11:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:19', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:21', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:23', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

FDA-CBER-2022-1614-0711823

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:26', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:28', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:30', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'None (0)'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:33', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered 'No (N)'	System	07 Aug 2020 19:42:44

FDA-CBER-2022-1614-0711827

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:11:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T14:42:41', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cc047361-9314-4c2d-ae2c-2d08044d4968'	System	07 Aug 2020 19:42:44
User entered '07 Aug 2020 14:42'	System	07 Aug 2020 19:42:44

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 13:57'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 16:27'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:47', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:24:55', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:10', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:11:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:27', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'None (0)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered 'No (N)'	System	07 Aug 2020 22:25:53

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-07T17:25:50', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6d8e6d06-b269-41c0-8232-6f41cdce2ac1'	System	07 Aug 2020 22:25:53
User entered '07 Aug 2020 17:25'	System	07 Aug 2020 22:25:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '07 Aug 2020 17:22'	System	07 Aug 2020 18:42:05

FDA-CBER-2022-1614-0711840

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 2'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:11:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:47', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:11:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:52', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:11:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:37:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:11:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:12', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'None (0)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:20', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered 'No (N)'	System	08 Aug 2020 19:38:31

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:11:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-08T14:38:26', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '6a50bfc8-5572-45cd-8948-c883e2f87665'	System	08 Aug 2020 19:38:31
User entered '08 Aug 2020 14:38'	System	08 Aug 2020 19:38:31

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:11:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 3'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:11:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:31', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:11:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:38', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:11:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:11:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:53', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:11:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:04:58', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:11:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:05:05', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'None (0)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:05:12', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered 'No (N)'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-09T12:05:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c4560b89-03de-4d15-b79a-5943fb7ad4b9'	System	09 Aug 2020 17:05:20
User entered '09 Aug 2020 12:05'	System	09 Aug 2020 17:05:20

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 4'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:02:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:06', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:11', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:17', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:11:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:24', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'None (0)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:34', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered 'No (N)'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-10T13:03:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '950bb268-09b6-4cc7-b0bd-4cccb54a543c'	System	10 Aug 2020 18:03:45
User entered '10 Aug 2020 13:03'	System	10 Aug 2020 18:03:45

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 5'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:11:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:51', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:11:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:30:55', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:11:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:11:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:08', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:11:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:16', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:11:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:24', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'None (0)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:32', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered 'No (N)'	System	11 Aug 2020 18:31:41

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-11T13:31:38', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '3216189b-0191-496b-a837-db2ed92b7cf7'	System	11 Aug 2020 18:31:41
User entered '11 Aug 2020 13:31'	System	11 Aug 2020 18:31:41

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:11:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 6'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:11:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:11:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:37', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:11:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:41', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:11:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:50', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:11:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:32:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'None (0)'	System	12 Aug 2020 18:33:12

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:33:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered 'No (N)'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-12T13:33:08', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '41e2d5f9-ea68-4849-861d-b950314272c0'	System	12 Aug 2020 18:33:12
User entered '12 Aug 2020 13:33'	System	12 Aug 2020 18:33:12

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 7'	System	07 Aug 2020 18:42:05

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:11:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:36', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:11:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:42', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:11:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:46', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:11:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:51', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:11:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:01:57', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:11:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:02:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'None (0)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:02:22', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered 'No (N)'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-08-13T12:02:29', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c8b3b79e-df6a-488a-b628-31c6547d341d'	System	13 Aug 2020 17:02:35
User entered '13 Aug 2020 12:02'	System	13 Aug 2020 17:02:35

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:42:05

US3252075

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:11:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:30
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:16:33
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:48

US3252075

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:30
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:16:33
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:48

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:30
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:16:33
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:48

US3252075
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:30
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:16:33
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:48

US3252075

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:30
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 05:00:24
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:25:54

US3252075
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:43:30
User entered '1'	System	14 Sep 2020 02:25:54

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:34
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:08:12
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:37

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:34
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:08:12
User entered empty.	Nancy Torrence (b) (4)	14 Sep 2020 02:26:37
	(b) (4)	

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:34
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:08:12
User entered empty.	Nancy Torrence (b) (4)	14 Sep 2020 02:26:37
	(b) (4)	

US3252075

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:34
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:08:12
User closed query '"If contact not made, please provide comments" is not completed. Please note this patient was in the Convalescent Period during this visit, so this safety call was not expected. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 19:08:01
Query '"If contact not made, please provide comments" is not completed. Please note this patient was in the Convalescent Period during this visit, so this safety call was not expected. ' answered with 'UPDATED' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	29 Dec 2020 05:51:53
User entered 'this patient was in the Convalescent Period during this visit, so this safety call was not expected.' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	29 Dec 2020 05:51:41
User opened query '"If contact not made, please provide comments" is not completed. Please note this patient was in the Convalescent Period during this visit, so this safety call was not expected. ' (Site from CRA).	(b) (4), (b) (6)	28 Dec 2020 21:17:15
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:37

US3252075
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:34
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 06:14:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:48
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:42

US3252075

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:41:34
User entered '1'	System	14 Sep 2020 02:26:48
User entered empty.	System	14 Sep 2020 02:26:42

US3252075
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:08
DataPoint Verified.		22 Apr 2021 04:57:37
Query 'There is no source available to verify this is not completed. Please review. ' canceled (Site from CRA).		22 Apr 2021 04:57:27
User opened query 'There is no source available to verify this is not completed. Please review. ' (Site from CRA).		20 Apr 2021 01:13:43
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:55

US3252075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:08
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 04:57:37
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:55

US3252075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:08
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 04:57:37
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:55

US3252075

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:08
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 04:57:37
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:26:55

US3252075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:08
DataPoint Verified.		22 Apr 2021 04:57:48
Query 'There is no source available to verify this is not completed. Please review. ' canceled (Site from CRA).		22 Apr 2021 04:57:46
User opened query 'There is no source available to verify this is not completed. Please review. ' (Site from CRA).		20 Apr 2021 01:13:54
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:27:00

US3252075

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:34:08
User entered '1'	System	14 Sep 2020 02:27:00

US3252075
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:10:50
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:27:41

Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:10:50
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 15:16:45
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit date is correct. Patient was out of window due to being in the illness visit' (Site from System).	Uche Ehiemua (b) (4) (b) (4)	12 Nov 2020 22:30:41
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	06 Nov 2020 22:01:34
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 20:32:20
Amendment Manager: Query text changed to "Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."	System	16 Sep 2020 23:47:38
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Subject visit is within the window.' (Site from System).	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 04:32:26
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 02:27:41
User entered '12 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:27:41

US3252075

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:10:50
User signature succeeded.	Joel Solis　(b) (4)	04 Mar 2021 23:21:14
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:27:41

US3252075
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'VISIT2'	System	14 Sep 2020 02:27:41

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '12 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '13:10'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '12 Sep 2020 13:10'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '98.8' F	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:11:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '89'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'bpm'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '16'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'breaths/min'	System	14 Sep 2020 02:31:28

FDA-CBER-2022-1614-0711941

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '141'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'mmHg'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '81'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'mmHg'	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:31:28

FDA-CBER-2022-1614-0711950

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

FDA-CBER-2022-1614-0711956

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:31:28

US3252075

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:23
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:31:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:31:28

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:33
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:34:19

US3252075

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:11:33
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:34:19

US3252075
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:11:52
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:10
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:11:52
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:10
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	14 Sep 2020 02:33:07
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:33:07
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	14 Sep 2020 02:32:58
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:10
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:11:52
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:32:58

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:10
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:10
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:10
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:10
User entered empty.	System	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:32:58

US3252075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:45
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:38:37

US3252075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:45
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '12 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:38:37

US3252075

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:45
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '13:14'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:38:37

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '12 Sep 2020 13:14'	System	14 Sep 2020 02:38:37

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:59
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '12 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:11:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:59
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:59
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '13:21'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '12 Sep 2020 13:21'	System	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:59
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

US3252075

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:12:59
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:35:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered empty.	System	14 Sep 2020 02:35:18

Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:13:05
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	14 Sep 2020 02:37:47

US3252075
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '1'	System	14 Sep 2020 02:37:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3252075
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:31
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:28

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:31
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '21 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:28

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:31
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:28

US3252075

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:31
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered empty.	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:28

Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:14:36
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	22 Sep 2020 02:48:33

US3252075
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '1'	System	22 Sep 2020 02:48:33

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:19:21
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:09

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:19:21
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '26 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:09

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:19:21
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:09

US3252075

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:19:21
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered empty.	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:09

US3252075

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:19:24
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:16

US3252075
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '1'	System	28 Sep 2020 01:35:16

US3252075
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:21:52
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:54

US3252075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:21:52
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered '6 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:54

US3252075

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:21:52
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:54

FDA-CBER-2022-1614-0712003

US3252075
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:21:52
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered empty.	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:54

US3252075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:21:56
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:20:09
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	07 Oct 2020 03:23:59

US3252075

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '1'	System	07 Oct 2020 03:23:59

US3252075
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:17
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:44:48

US3252075
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:17
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 14:44:48

US3252075

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:17
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Home (Home)'	(b) (4), (b) (6)	12 Nov 2020 14:44:48

US3252075
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'VISIT3'	System	12 Nov 2020 14:44:48

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '12:57'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '10 Oct 2020 12:57'	System	12 Nov 2020 14:45:31

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '98.7' F	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '73'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'bpm'	System	12 Nov 2020 14:45:31

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '15'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'breaths/min'	System	12 Nov 2020 14:45:31

FDA-CBER-2022-1614-0712021

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '132'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

FDA-CBER-2022-1614-0712022

US3252075
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'mmHg'	System	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:48
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '75'	(b) (4), (b) (6)	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered 'mmHg'	System	12 Nov 2020 14:45:31

US3252075

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39

US3252075

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:54
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 14:45:41

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:23:54
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:45:41

FDA-CBER-2022-1614-0712029

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:24:03
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:45:59

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:24:03
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:39:20
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample is NOT missing in PPD, requisition number is 1F617405987. Reports for this visit were sent back on Jan 29th.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 16:55:41
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 10OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:54:02
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Nov 2020 14:45:59

FDA-CBER-2022-1614-0712031

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:24:03
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered '13:21'	(b) (4), (b) (6)	12 Nov 2020 14:45:59

US3252075

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '10 Oct 2020 13:21'	System	12 Nov 2020 14:45:59

US3252075
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:24:07
User signature succeeded.	Joel Solis (b) (4)	04 Mar 2021 23:21:14
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:15

US3252075

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '1'	System	12 Nov 2020 02:43:15

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 64'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 71'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-10-15T12:49:05', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f8f3673d-d825-43e4-b36e-4b21082d1a40'	System	15 Oct 2020 17:49:22
User entered 'No (N)'	System	15 Oct 2020 17:49:22

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-10-15T12:49:10', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f8f3673d-d825-43e4-b36e-4b21082d1a40'	System	15 Oct 2020 17:49:22
User entered 'No (N)'	System	15 Oct 2020 17:49:22

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-10-15T12:49:16', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f8f3673d-d825-43e4-b36e-4b21082d1a40'	System	15 Oct 2020 17:49:22
User entered '15 Oct 2020 12:49:16'	System	15 Oct 2020 17:49:22

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 78'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-10-21T07:49:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6d5e0d8-3f74-4c84-b6db-f1ab9e8216d8'	System	21 Oct 2020 12:49:30
User entered 'No (N)'	System	21 Oct 2020 12:49:30

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-10-21T07:49:15', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6d5e0d8-3f74-4c84-b6db-f1ab9e8216d8'	System	21 Oct 2020 12:49:30
User entered 'No (N)'	System	21 Oct 2020 12:49:30

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-10-21T07:49:25', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6d5e0d8-3f74-4c84-b6db-f1ab9e8216d8'	System	21 Oct 2020 12:49:30
User entered '21 Oct 2020 07:49:25'	System	21 Oct 2020 12:49:30

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 92'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 99'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-11T07:34:15', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '7769cd69-9f00-447c-80fb-c10888e1a022'	System	11 Nov 2020 13:34:31
User entered 'No (N)'	System	11 Nov 2020 13:34:31

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-11T07:34:20', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '7769cd69-9f00-447c-80fb-c10888e1a022'	System	11 Nov 2020 13:34:31
User entered 'No (N)'	System	11 Nov 2020 13:34:31

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-11T07:34:26', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '7769cd69-9f00-447c-80fb-c10888e1a022'	System	11 Nov 2020 13:34:31
User entered '11 Nov 2020 07:34:26'	System	11 Nov 2020 13:34:31

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:47
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered 'Day 106'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 18:42:05

US3252075

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:42:05
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 18:42:05

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2020-11-19T18:20:28', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4e6d37e6-16a9-444e-8fbe-3cf617b38c46'	System	20 Nov 2020 00:20:41
User entered 'No (N)'	System	20 Nov 2020 00:20:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-11-19T18:20:33', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4e6d37e6-16a9-444e-8fbe-3cf617b38c46'	System	20 Nov 2020 00:20:41
User entered 'No (N)'	System	20 Nov 2020 00:20:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-19T18:20:38', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4e6d37e6-16a9-444e-8fbe-3cf617b38c46'	System	20 Nov 2020 00:20:41
User entered '19 Nov 2020 18:20:38'	System	20 Nov 2020 00:20:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2020-11-22T19:36:30', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '39b8c22d-872a-4486-b47d-e104e51de338'	System	23 Nov 2020 01:36:41
User entered 'No (N)'	System	23 Nov 2020 01:36:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-11-22T19:36:35', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '39b8c22d-872a-4486-b47d-e104e51de338'	System	23 Nov 2020 01:36:41
User entered 'No (N)'	System	23 Nov 2020 01:36:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-22T19:36:39', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '39b8c22d-872a-4486-b47d-e104e51de338'	System	23 Nov 2020 01:36:41
User entered '22 Nov 2020 19:36:39'	System	23 Nov 2020 01:36:41

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:57:11

FDA-CBER-2022-1614-0712150

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2020-11-30T13:57:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b9f7960e-54b3-48fd-8451-756e173a2c6c'	System	30 Nov 2020 19:57:14
User entered 'No (N)'	System	30 Nov 2020 19:57:14

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-11-30T13:57:07', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b9f7960e-54b3-48fd-8451-756e173a2c6c'	System	30 Nov 2020 19:57:14
User entered 'No (N)'	System	30 Nov 2020 19:57:14

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-11-30T13:57:11', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b9f7960e-54b3-48fd-8451-756e173a2c6c'	System	30 Nov 2020 19:57:14
User entered '30 Nov 2020 13:57:11'	System	30 Nov 2020 19:57:14

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

FDA-CBER-2022-1614-0712155

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2020-12-07T20:20:42', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'fda9bf01-24bd-47a5-a335-ffa405a930d6'	System	08 Dec 2020 02:20:53
User entered 'No (N)'	System	08 Dec 2020 02:20:53

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-12-07T20:20:44', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'fda9bf01-24bd-47a5-a335-ffa405a930d6'	System	08 Dec 2020 02:20:53
User entered 'No (N)'	System	08 Dec 2020 02:20:53

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-12-07T20:20:48', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'fda9bf01-24bd-47a5-a335-ffa405a930d6'	System	08 Dec 2020 02:20:53
User entered '07 Dec 2020 20:20:48'	System	08 Dec 2020 02:20:53

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2020-12-20T20:04:49', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b63a3618-08fd-4ae2-8117-6d70b6b61efb'	System	21 Dec 2020 02:04:59
User entered 'No (N)'	System	21 Dec 2020 02:04:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-12-20T20:04:51', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b63a3618-08fd-4ae2-8117-6d70b6b61efb'	System	21 Dec 2020 02:04:59
User entered 'No (N)'	System	21 Dec 2020 02:04:59

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-12-20T20:04:55', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b63a3618-08fd-4ae2-8117-6d70b6b61efb'	System	21 Dec 2020 02:04:59
User entered '20 Dec 2020 20:04:55'	System	21 Dec 2020 02:04:59

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2020-12-28T20:28:18', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c3e346a1-fa6f-4f28-abf6-896638de69c6'	System	29 Dec 2020 02:28:30
User entered 'No (N)'	System	29 Dec 2020 02:28:30

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2020-12-28T20:28:23', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c3e346a1-fa6f-4f28-abf6-896638de69c6'	System	29 Dec 2020 02:28:30
User entered 'No (N)'	System	29 Dec 2020 02:28:30

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2020-12-28T20:28:27', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c3e346a1-fa6f-4f28-abf6-896638de69c6'	System	29 Dec 2020 02:28:30
User entered '28 Dec 2020 20:28:27'	System	29 Dec 2020 02:28:30

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-01-03T18:38:49', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c500eeb-416e-4641-b530-97ad5af8ecbb'	System	04 Jan 2021 00:39:01
User entered 'No (N)'	System	04 Jan 2021 00:39:01

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-01-03T18:38:55', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c500eeb-416e-4641-b530-97ad5af8ecbb'	System	04 Jan 2021 00:39:01
User entered 'No (N)'	System	04 Jan 2021 00:39:01

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-01-03T18:38:58', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '0c500eeb-416e-4641-b530-97ad5af8ecbb'	System	04 Jan 2021 00:39:01
User entered '03 Jan 2021 18:38:58'	System	04 Jan 2021 00:39:01

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-01-12T20:32:58', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a43f7721-c98b-4da4-8729-a05509bf7207'	System	13 Jan 2021 02:33:07
User entered 'No (N)'	System	13 Jan 2021 02:33:07

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-01-12T20:33:02', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a43f7721-c98b-4da4-8729-a05509bf7207'	System	13 Jan 2021 02:33:07
User entered 'No (N)'	System	13 Jan 2021 02:33:07

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-01-12T20:33:05', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'a43f7721-c98b-4da4-8729-a05509bf7207'	System	13 Jan 2021 02:33:07
User entered '12 Jan 2021 20:33:05'	System	13 Jan 2021 02:33:07

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-01-21T20:38:13', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '751595f6-6ab2-4369-b8c7-1708907ef0ab'	System	22 Jan 2021 02:38:27
User entered 'No (N)'	System	22 Jan 2021 02:38:27

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-01-21T20:38:20', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '751595f6-6ab2-4369-b8c7-1708907ef0ab'	System	22 Jan 2021 02:38:27
User entered 'No (N)'	System	22 Jan 2021 02:38:27

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-01-21T20:38:24', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '751595f6-6ab2-4369-b8c7-1708907ef0ab'	System	22 Jan 2021 02:38:27
User entered '21 Jan 2021 20:38:24'	System	22 Jan 2021 02:38:27

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-01-25T22:06:04', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '745cee3c-56a8-4ab9-827e-3c7c146da3f0'	System	26 Jan 2021 04:06:17
User entered 'No (N)'	System	26 Jan 2021 04:06:17

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-01-25T22:06:10', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '745cee3c-56a8-4ab9-827e-3c7c146da3f0'	System	26 Jan 2021 04:06:17
User entered 'No (N)'	System	26 Jan 2021 04:06:17

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-01-25T22:06:14', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '745cee3c-56a8-4ab9-827e-3c7c146da3f0'	System	26 Jan 2021 04:06:17
User entered '25 Jan 2021 22:06:14'	System	26 Jan 2021 04:06:17

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-01-31T00:01:40', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '61c6201c-c873-48b7-b62c-2074773a710f'	System	31 Jan 2021 06:02:29
User entered 'No (N)'	System	31 Jan 2021 06:02:29

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-01-31T00:01:45', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '61c6201c-c873-48b7-b62c-2074773a710f'	System	31 Jan 2021 06:02:29
User entered 'No (N)'	System	31 Jan 2021 06:02:29

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-01-31T00:01:49', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '61c6201c-c873-48b7-b62c-2074773a710f'	System	31 Jan 2021 06:02:29
User entered '31 Jan 2021 00:01:49'	System	31 Jan 2021 06:02:29

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-02-07T16:08:33', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '052c6f2d-a00e-4d30-a2b9-fe80f0aa26ab'	System	07 Feb 2021 22:08:43
User entered 'No (N)'	System	07 Feb 2021 22:08:43

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-02-07T16:08:37', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '052c6f2d-a00e-4d30-a2b9-fe80f0aa26ab'	System	07 Feb 2021 22:08:43
User entered 'No (N)'	System	07 Feb 2021 22:08:43

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-02-07T16:08:41', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '052c6f2d-a00e-4d30-a2b9-fe80f0aa26ab'	System	07 Feb 2021 22:08:43
User entered '07 Feb 2021 16:08:41'	System	07 Feb 2021 22:08:43

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-02-15T12:07:47', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cf06ed32-d954-4e52-8650-fed2c0f2d7c4'	System	15 Feb 2021 18:10:53
User entered 'No (N)'	System	15 Feb 2021 18:10:53

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-02-15T12:07:52', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cf06ed32-d954-4e52-8650-fed2c0f2d7c4'	System	15 Feb 2021 18:10:53
User entered 'No (N)'	System	15 Feb 2021 18:10:53

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-02-15T12:07:56', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'cf06ed32-d954-4e52-8650-fed2c0f2d7c4'	System	15 Feb 2021 18:10:53
User entered '15 Feb 2021 12:07:56'	System	15 Feb 2021 18:10:53

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-02-21T15:42:38', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c5ade88a-2023-4062-8520-a5469bedd29d'	System	21 Feb 2021 21:42:52
User entered 'No (N)'	System	21 Feb 2021 21:42:52

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-02-21T15:42:43', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c5ade88a-2023-4062-8520-a5469bedd29d'	System	21 Feb 2021 21:42:52
User entered 'No (N)'	System	21 Feb 2021 21:42:52

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-02-21T15:42:48', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'c5ade88a-2023-4062-8520-a5469bedd29d'	System	21 Feb 2021 21:42:52
User entered '21 Feb 2021 15:42:48'	System	21 Feb 2021 21:42:52

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-02-28T17:23:07-06:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'eb7f59b7-41b8-4c69-9eb6-5833e470ba28'	System	28 Feb 2021 23:23:20
User entered 'No (N)'	System	28 Feb 2021 23:23:20

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-02-28T17:23:12-06:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'eb7f59b7-41b8-4c69-9eb6-5833e470ba28'	System	28 Feb 2021 23:23:20
User entered 'No (N)'	System	28 Feb 2021 23:23:20

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-02-28T17:23:16-06:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'eb7f59b7-41b8-4c69-9eb6-5833e470ba28'	System	28 Feb 2021 23:23:20
User entered '28 Feb 2021 17:23:16'	System	28 Feb 2021 23:23:20

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-03-07T13:07:32-06:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '84db93ee-edb0-4c27-a51e-a7a3cf32f88e'	System	07 Mar 2021 19:07:42
User entered 'No (N)'	System	07 Mar 2021 19:07:42

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-03-07T13:07:36-06:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '84db93ee-edb0-4c27-a51e-a7a3cf32f88e'	System	07 Mar 2021 19:07:42
User entered 'No (N)'	System	07 Mar 2021 19:07:42

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-03-07T13:07:40-06:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '84db93ee-edb0-4c27-a51e-a7a3cf32f88e'	System	07 Mar 2021 19:07:42
User entered '07 Mar 2021 13:07:40'	System	07 Mar 2021 19:07:42

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-03-16T13:07:38-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6f60053-7127-4ab3-a112-5e97c58a0648'	System	16 Mar 2021 18:07:51
User entered 'No (N)'	System	16 Mar 2021 18:07:51

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-03-16T13:07:42-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6f60053-7127-4ab3-a112-5e97c58a0648'	System	16 Mar 2021 18:07:51
User entered 'No (N)'	System	16 Mar 2021 18:07:51

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-03-16T13:07:45-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b6f60053-7127-4ab3-a112-5e97c58a0648'	System	16 Mar 2021 18:07:51
User entered '16 Mar 2021 13:07:45'	System	16 Mar 2021 18:07:51

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-03-21T00:01:33-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '273dc6cf-f084-4e37-99ca-fca71f4d4563'	System	21 Mar 2021 05:01:48
User entered 'No (N)'	System	21 Mar 2021 05:01:48

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-03-21T00:01:40-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '273dc6cf-f084-4e37-99ca-fca71f4d4563'	System	21 Mar 2021 05:01:48
User entered 'No (N)'	System	21 Mar 2021 05:01:48

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-03-21T00:01:43-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '273dc6cf-f084-4e37-99ca-fca71f4d4563'	System	21 Mar 2021 05:01:48
User entered '21 Mar 2021 00:01:43'	System	21 Mar 2021 05:01:48

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-03-30T19:45:04-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b0161917-b422-4faa-a7ed-5360db04ed71'	System	31 Mar 2021 00:45:23
User entered 'No (N)'	System	31 Mar 2021 00:45:23

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-03-30T19:45:09-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b0161917-b422-4faa-a7ed-5360db04ed71'	System	31 Mar 2021 00:45:23
User entered 'No (N)'	System	31 Mar 2021 00:45:23

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-03-30T19:45:16-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'b0161917-b422-4faa-a7ed-5360db04ed71'	System	31 Mar 2021 00:45:23
User entered '30 Mar 2021 19:45:16'	System	31 Mar 2021 00:45:23

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-04-07T21:18:15-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4219c4cb-dc8e-41f4-a254-2842622fdfd8'	System	08 Apr 2021 02:18:27
User entered 'No (N)'	System	08 Apr 2021 02:18:27

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-04-07T21:18:18-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4219c4cb-dc8e-41f4-a254-2842622fdfd8'	System	08 Apr 2021 02:18:27
User entered 'No (N)'	System	08 Apr 2021 02:18:27

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-04-07T21:18:21-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4219c4cb-dc8e-41f4-a254-2842622fdfd8'	System	08 Apr 2021 02:18:27
User entered '07 Apr 2021 21:18:21'	System	08 Apr 2021 02:18:27

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-04-11T00:12:42-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4300882b-8e08-47b0-8830-ba41203e9718'	System	11 Apr 2021 05:12:58
User entered 'No (N)'	System	11 Apr 2021 05:12:58

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-04-11T00:12:48-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4300882b-8e08-47b0-8830-ba41203e9718'	System	11 Apr 2021 05:12:58
User entered 'No (N)'	System	11 Apr 2021 05:12:58

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-04-11T00:12:52-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4300882b-8e08-47b0-8830-ba41203e9718'	System	11 Apr 2021 05:12:58
User entered '11 Apr 2021 00:12:52'	System	11 Apr 2021 05:12:58

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-04-22T09:34:24-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '09352b80-88b1-43a3-ab6b-255a8d250c25'	System	22 Apr 2021 14:34:38
User entered 'No (N)'	System	22 Apr 2021 14:34:38

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-04-22T09:34:27-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '09352b80-88b1-43a3-ab6b-255a8d250c25'	System	22 Apr 2021 14:34:38
User entered 'No (N)'	System	22 Apr 2021 14:34:38

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-04-22T09:34:30-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '09352b80-88b1-43a3-ab6b-255a8d250c25'	System	22 Apr 2021 14:34:38
User entered '22 Apr 2021 09:34:30'	System	22 Apr 2021 14:34:38

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

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 (b1fbab22f878f305)', Time: '2021-04-27T20:35:50-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f58728a9-cd44-4d87-9b01-d914523adb2b'	System	29 Apr 2021 02:30:11
User entered 'No (N)'	System	29 Apr 2021 02:30:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Have you been exposed to someone with 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 (b1fbab22f878f305)', Time: '2021-04-27T20:35:54-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f58728a9-cd44-4d87-9b01-d914523adb2b'	System	29 Apr 2021 02:30:11
User entered 'No (N)'	System	29 Apr 2021 02:30:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-04-27T20:35:57-05:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: 'f58728a9-cd44-4d87-9b01-d914523adb2b'	System	29 Apr 2021 02:30:11
User entered '27 Apr 2021 20:35:57'	System	29 Apr 2021 02:30:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:57:11

FDA-CBER-2022-1614-0712284

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:57:11

FDA-CBER-2022-1614-0712303

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:57:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:57:11

FDA-CBER-2022-1614-0712447

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:57:11

FDA-CBER-2022-1614-0712459

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:57:11

FDA-CBER-2022-1614-0712501

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:11:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:57:11

US3252075

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:11:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:57:11

US3252075

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:11:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-02-27T21:06:58-06:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4404330c-e7f0-436a-8da7-41bbe4a1da0c'	System	28 Feb 2021 03:10:24
User entered 'No (N)'	System	28 Feb 2021 03:10:24

US3252075

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:11:52

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:34:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b1fbab22f878f305)', Time: '2021-02-27T21:07:02-06:00', User OID: 'PatientReportedOutcome (US3252075)', ODM File OID: '4404330c-e7f0-436a-8da7-41bbe4a1da0c'	System	28 Feb 2021 03:10:24
User entered '27 Feb 2021 21:07:02'	System	28 Feb 2021 03:10:24

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:27:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:38

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:27:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered '11 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:38

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:27:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Contact Not Made (CONTACT NOT MADE)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:38

FDA-CBER-2022-1614-0712511

US3252075

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:27:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Patient did not answer phone call, text or email.'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:38

US3252075

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:27:39
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	12 Nov 2020 02:43:46

US3252075

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:39
User entered '1'	System	12 Nov 2020 02:43:46

US3252075
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	Heather Davis (b) (4)	15 Apr 2021 19:07:38
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:23:14

US3252075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	15 Apr 2021 19:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered '11 Dec 2020'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:23:14

US3252075

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	15 Apr 2021 19:07:49
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Contact Not Made (CONTACT NOT MADE)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:23:14

US3252075
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	15 Apr 2021 19:08:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'left voice mail'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:23:14

US3252075

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	15 Apr 2021 19:08:36
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:23:19

Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
User entered '1'	System	05 Feb 2021 03:23:19

US3252075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	23 Apr 2021 06:05:16
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	22 Apr 2021 19:22:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:24
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:24:05

US3252075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.		23 Apr 2021 13:39:40
User closed query 'Per source contact was not attempted. Please review and reconcile. ' (Site from CRA).		23 Apr 2021 13:39:38
Query 'Per source contact was not attempted. Please review and reconcile. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 06:05:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 06:05:16
User opened query 'Per source contact was not attempted. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 02:01:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 19:22:21
Signature has been broken.		22 Apr 2021 19:22:21
User entered '9 Jan 2021' reason for change: Data Entry Error		22 Apr 2021 19:22:21
DataPoint Verified.		21 Apr 2021 14:43:24
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:24:05

US3252075

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.		23 Apr 2021 13:39:40
User entered empty; reason for change Data Entry Error		23 Apr 2021 06:05:16
DataPoint Un-verified.		22 Apr 2021 19:22:21
Signature has been broken.		22 Apr 2021 19:22:21
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error		22 Apr 2021 19:22:21
DataPoint Verified.		21 Apr 2021 14:43:24
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:24:05

US3252075
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.		23 Apr 2021 13:39:40
User entered empty; reason for change Data Entry Error		23 Apr 2021 06:05:16
DataPoint Un-verified.		22 Apr 2021 19:22:21
Signature has been broken.		22 Apr 2021 19:22:21
User entered 'Phone call missed.' reason for change: Data Entry Error		22 Apr 2021 19:22:21
DataPoint Verified.		21 Apr 2021 14:43:24
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Feb 2021 03:24:05

US3252075

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	Heather Davis (b) (4)	15 Apr 2021 19:07:59
	(b) (4)	
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Yes (Y)'	Joanna Gurrola Mahoney	05 Feb 2021 03:24:09
	(b) (4)	

US3252075
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
User entered '1'	System	05 Feb 2021 03:24:09

US3252075
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.		25 Apr 2021 16:17:11
User signature succeeded.		22 Apr 2021 18:45:32
DataPoint Un-verified.		22 Apr 2021 05:42:40
Signature has been broken.		22 Apr 2021 05:42:40
User entered 'Yes (Y)' reason for change: Data Entry Error		22 Apr 2021 05:42:40
DataPoint Verified.		21 Apr 2021 14:43:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 05:50:38

US3252075
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
Query 'This is what is in source, but please confirm date of attempted contact as this is out of the expected window of 06-12FEB2021. ' canceled (Site from CRA).		25 Apr 2021 22:52:55
User opened query 'This is what is in source, but please confirm date of attempted contact as this is out of the expected window of 06-12FEB2021. ' (Site from CRA).	(b) (4), (b) (6)	25 Apr 2021 16:24:56
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 16:17:14
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 05:42:40
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 05:42:40
User entered '14 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 05:42:40
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 05:50:38

US3252075
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 16:17:15
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 05:42:40
Signature has been broken.		22 Apr 2021 05:42:40
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error		22 Apr 2021 05:42:40
DataPoint Verified.		21 Apr 2021 14:43:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 05:50:38

US3252075
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	(b) (4), (b) (6)	25 Apr 2021 16:17:17
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 05:42:40
Signature has been broken.		22 Apr 2021 05:42:40
User entered 'patient missed safety call' reason for change: Data Entry Error		22 Apr 2021 05:42:40
DataPoint Verified.		21 Apr 2021 14:43:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 05:50:38

US3252075

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:43:39
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 05:03:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 05:03:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'No (N)'	(b) (4), (b) (6)	12 Feb 2021 05:50:42

US3252075
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:44:00
User entered '1'	System	10 Mar 2021 05:03:13
User entered empty.	System	12 Feb 2021 05:50:42

US3252075
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User closed query 'Please complete the vitals data on the following CRF. If ND please records NO.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 13:43:32
Query 'Please complete the vitals data on the folowing CRF. If ND please records NO.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 07:46:01
User opened query 'Please complete the vitals data on the folowing CRF. If ND please records NO.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:46:23
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:44:50
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 05:03:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:44:50
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 05:03:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:44:50
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Mar 2021 05:03:24

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User entered 'VISIT4'	System	10 Mar 2021 05:03:24

US3252075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 07:45:49

US3252075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User entered empty.	System	23 Apr 2021 07:45:49

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

US3252075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User entered empty.	System	23 Apr 2021 07:45:49

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User entered empty.	System	23 Apr 2021 07:45:49

US3252075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User entered empty.	System	23 Apr 2021 07:45:49

US3252075

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:43:28
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 07:45:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User entered empty.	System	23 Apr 2021 07:45:49

FDA-CBER-2022-1614-0712551

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29

US3252075
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:46:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 05:03:30

US3252075
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:11:52
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:46:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 05:03:30

US3252075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 05:03:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 05:03:52

FDA-CBER-2022-1614-0712557

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:19
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '10:55'	(b) (4), (b) (6)	10 Mar 2021 05:03:52

FDA-CBER-2022-1614-0712558

US3252075

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User entered '9 Mar 2021 10:55'	System	10 Mar 2021 05:03:52

US3252075
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:47:24
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 05:04:06

US3252075

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:38:29
User entered '1'	System	10 Mar 2021 05:04:06

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:11:52

Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (13Aug 2020). Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:23:18
Query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (13Aug 2020). Please review and reconcile. ' answered with 'per source correct as is' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 10:02:51
User opened query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (13Aug 2020). Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:35:16
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:43:01
User entered '13 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 15:13:24
User entered '07 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:36:35
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:29:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:11:52
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'In source under Follow Up Safety, date of contact is timed at 16:59. Please review and reconcile. ?' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:06:38
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 22:06:34
Query 'In source under Follow Up Safety, date of contact is timed at 16:59. Please review and reconcile. ?' answered with 'Source reviewed and reconciled.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	28 Oct 2020 14:10:48
User entered '16:59' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	28 Oct 2020 14:10:39
User opened query 'In source under Follow Up Safety, date of contact is timed at 16:59. Please review and reconcile. ?' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:43:45
Query 'In source under follow up safety, date of contact is timed at 16:59. Please review and reconcile. ' canceled (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:32:58
User opened query 'In source under follow up safety, date of contact is timed at 16:59. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:45:06
User entered '00:00'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:29:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:11:52
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:37
User entered '13 Aug 2020 16:59'	System	28 Oct 2020 14:10:39
User entered '13 Aug 2020 00:00'	System	19 Oct 2020 15:13:24
User entered '07 Aug 2020 00:00'	System	17 Aug 2020 16:36:35
User entered '13 Aug 2020 00:00'	System	17 Aug 2020 16:29:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:11:52

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 01:33:37
DataPoint Un-verified.		27 Oct 2020 19:21:05
DataPoint Verified.		21 Oct 2020 18:43:03
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:29:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:11:52

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:37
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:43:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	16 Oct 2020 17:20:53
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Aug 2020 21:14:51
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:29:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Symptom log is not present in source.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:20:25
User opened query 'Symptom log is not present in source.' (Site from CRA).		23 Oct 2020 14:44:31
User entered 'Day 2 (Day 2)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:50:53
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:22
User entered '14 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:50:55
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:23
User entered '0'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:50:58
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:29
User entered '99'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:00
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:31
User entered '97.9' F	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:02
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:40
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:05
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:43
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:11
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:46
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:13
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:50
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

FDA-CBER-2022-1614-0712576

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:16
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:22:58
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:36
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:43
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:06
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:45
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:13
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:48
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:28
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:49
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:31
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:52
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:34
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:55
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:38
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

FDA-CBER-2022-1614-0712584

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:58
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:42
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:51:59
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:44
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:02
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:46
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

FDA-CBER-2022-1614-0712587

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:04
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:23:49
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:59:59

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 3 (Day 3)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:38
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:37
User entered '15 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:40
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:38
User entered '0'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:44
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:40
User entered '98'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	19 Oct 2020 20:02:52

FDA-CBER-2022-1614-0712593

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:46
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:43
User entered '97.8' F	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:50
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:46
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:54
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:50
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:56
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:27:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:52:59
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:13
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per source, fatigue reported as "none". Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:20:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:02
Query 'Per source, fatigue reported as "none". Please review and reconcile. ' answered with 'updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:16:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:16:13
User opened query 'Per source, fatigue reported as "none". Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:06:06
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:05:23
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:07
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:16
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:12
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:18
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:28:16
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:26
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:38
DataPoint Un-verified.		27 Oct 2020 20:06:55
DataPoint Verified.		23 Oct 2020 15:28:20
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:31
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:39
DataPoint Un-verified.		27 Oct 2020 20:06:58
DataPoint Verified.		23 Oct 2020 15:28:42
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:33
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:42
DataPoint Un-verified.		27 Oct 2020 20:06:59
DataPoint Verified.		23 Oct 2020 15:28:47
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:37
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:47
DataPoint Un-verified.		27 Oct 2020 20:07:03
DataPoint Verified.		23 Oct 2020 15:28:55
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:43
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:20:51
DataPoint Un-verified.		27 Oct 2020 20:07:05
DataPoint Verified.		23 Oct 2020 15:28:59
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:45
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:03
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

FDA-CBER-2022-1614-0712607

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:47
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:07
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:50
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:09
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:11:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:53:51
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:29:12
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 20:02:52

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Symptom log for Day 1 is not present in source. ? ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:25:58
User opened query 'Symptom log for Day 1 is not present in source. ? ' (Site from CRA).		23 Oct 2020 15:20:45
User entered 'Day 1 (Day 1)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:44:42
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (13AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:58:10
Query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (13AUG2020) or update accordingly' answered with 'Subject started Symptoms on 13Aug2020 only.' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:17:11
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (13AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:15:29
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:25:52
User entered '13 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47
User entered '13 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:44:44
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:46
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:44:40
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:43
User entered '99'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:44:46
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:47
User entered '98.7' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:44:48
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:51
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:00
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:54
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:52

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:02
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:11:52

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:03
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:29:59
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:05
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:09
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:04
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:11
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:19
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:12
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:23
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:15
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:17
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:29
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:18
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:35
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

FDA-CBER-2022-1614-0712627

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:21
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:39
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:27
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:42
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:32
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:44
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:33
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:48
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:11:52
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:47:34
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:30:50
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:23:51

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Source is not available in CRIO. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:13:40
User opened query 'Source is not available in CRIO. ' (Site from CRA).		23 Oct 2020 15:47:41
User entered 'Day 4 (Day 4)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:13
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:45
Query 'Day 4 symptom log source is not updated. ' canceled (Site from CRA).		27 Oct 2020 20:13:32
User opened query 'Day 4 symptom log source is not updated. ' (Site from CRA).		23 Oct 2020 15:31:37
DataPoint Un-verified.		23 Oct 2020 15:31:00
DataPoint Verified.		23 Oct 2020 15:29:34
User entered '16 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47
User entered '16 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:52

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:20
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:52
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:21
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:55
User entered '97'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:23
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:57
User entered '96.9' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:25
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:13:59
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:28
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:09
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:32
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:13
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:35
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:17
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:38
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:19
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:43
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:14:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:45
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:40
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:48
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:45
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:52
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

FDA-CBER-2022-1614-0712647

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:54
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:00
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:54:58
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:03
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:02
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:07
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:05
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:09
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:06
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:12
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:08
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:15
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:11:52
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:11
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:17
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:25:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Source is not uploaded in CRIO.' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:20:09
User opened query 'Source is not uploaded in CRIO.' (Site from CRA).		23 Oct 2020 16:00:49
User entered 'Day 5 (Day 5)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:47
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:37
User entered '17 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47
User entered '17 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:48
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:10
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:52
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:14
User entered '99'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	21 Oct 2020 15:28:49

FDA-CBER-2022-1614-0712659

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:53
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:16
User entered '98.9' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:56
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:19
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:55:58
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:28
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:01
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:31
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:04
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:35
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:06
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:37
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:10
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:40
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:13
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:47
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:16
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:49
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:19
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:54
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:22
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:58
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:27
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:04
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:30
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:08
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:34
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:12
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:36
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:18
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:38
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:11:52
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:56:39
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:28:49

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Source is not updated in CRIO. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:27:19
User opened query 'Source is not updated in CRIO. ' (Site from CRA).		23 Oct 2020 16:01:13
User entered 'Day 6 (Day 6)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:06
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:23
User entered '18 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47
User entered '18 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:07
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:25
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:11
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:43
User entered '99'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	21 Oct 2020 15:45:20

FDA-CBER-2022-1614-0712681

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:13
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per source, temperature is 97.6. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:53:07
DataPoint Verified.		05 Nov 2020 16:52:56
Query 'Per source, temperature is 97.6. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:17:01
User entered '97.6' F reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:16:56
User opened query 'Per source, temperature is 97.6. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:28:06
User entered '99' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:15
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:09
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:19
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:12
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:25
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:15
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:28
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:17
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:30
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:36
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:22
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:39
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:42
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:33
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:45
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:48
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:38
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:51
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:42
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

FDA-CBER-2022-1614-0712693

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:53
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:47
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:55
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:49
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:57:58
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:52
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:00
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:54
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:11:52
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:03
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:55
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:45:20

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Source not uploaded to CRIO. ' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:32:39
User opened query 'Source not uploaded to CRIO. ' (Site from CRA).		23 Oct 2020 16:01:48
User entered 'Day 7 (Day 7)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:27
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:32:44
User entered '19 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:52

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:30
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:32:47
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:35
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:32:54
User entered '97'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	21 Oct 2020 16:12:47

FDA-CBER-2022-1614-0712703

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:38
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:32:56
User entered '98.9' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:49
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:33:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:51
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:00
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:52

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:58:55
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:52

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:59:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:04
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:59:17
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:08
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:59:20
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:10
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:59:23
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:34:13
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:59:40
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:43
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:59:45
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:46
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:59:47
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:48
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

FDA-CBER-2022-1614-0712714

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 18:59:52
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:51
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:02
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:55
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:05
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:48:00
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:07
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:47:58
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:11:52

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:09
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:48:03
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:11:52
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:12
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:48:05
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:12:47

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 8 (Day 8)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:31
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Symptom Log is not available in CRIO. Please provide source for review.' canceled (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:50:17
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:15
User opened query 'Symptom Log is not available in CRIO. Please provide source for review.' (Site from CRA).		23 Oct 2020 16:25:02
User entered '20 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:33
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:18
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:35
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:22
User entered '99'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	21 Oct 2020 16:28:06

FDA-CBER-2022-1614-0712725

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:37
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:23
User entered '97.8' F	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:41
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:28
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:43
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:36
User entered 'Moderate (Moderate)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:44
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:40
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:48
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:43
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:52
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:50
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:55
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:50:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:00:58
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:03
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:01
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:06
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:04
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:09
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:07
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:13
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:15
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:19
User entered 'Mild (Mild)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:12
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:24
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:18
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:21
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:29
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:23
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:32
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:11:52
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 19:01:25
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:51:34
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:28:06

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 9 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).		26 Apr 2021 10:17:30
Query 'Per CDM: Please verify that Symptom Log Line 9 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:08:24
User opened query 'Per CDM: Please verify that Symptom Log Line 9 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:03:48
Query 'Per CDM: Please verify that Symptom Log Line 11 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' canceled (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:03:32
User opened query 'Per CDM: Please verify that Symptom Log Line 11 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:03:23
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 9 (Day 9)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:56:19
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:56:53
Query 'Symptom Log is not available in CRIO. Please provide source for review.' canceled (Site from CRA).		23 Oct 2020 16:28:25
User opened query 'Symptom Log is not available in CRIO. Please provide source for review.' (Site from CRA).		23 Oct 2020 16:28:18
User entered '21 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14
User entered '21 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:56:55
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:45
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:56:58
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:45:44
User entered empty.	System	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:57:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:57:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:09
Query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log. ? ' answered with 'this has been updated.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log. ? ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:08:03
Query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:07:48

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Chills

Audit	User	Time (GMT)
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:57:35
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:18
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:21
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:11:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:07:40
Signature has been broken.		22 Apr 2021 07:07:40
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:07:40
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:18:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:40:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 10 (Day 10)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:58:49
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:00:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 19:00:15
User entered '22 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 18:42:14
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:42
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).		05 Nov 2020 17:01:39
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:43
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:00:55
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:42
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:46:36
User entered empty.	System	21 Oct 2020 18:42:14

FDA-CBER-2022-1614-0712770

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:44
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:01:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:46
Query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log.' answered with 'this has been updated. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
Query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' canceled (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:08:36
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" or blank should be selected for all symptoms in this log.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 22:08:30
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 20:59:05
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:01:52
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:17
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

FDA-CBER-2022-1614-0712776

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:27
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

FDA-CBER-2022-1614-0712784

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:11:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:46:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:02:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:20:25
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:00:15
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 18:42:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 11 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:18:00
Query 'Per CDM: Please verify that Symptom Log Line 11 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:12:46
User opened query 'Per CDM: Please verify that Symptom Log Line 11 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:04:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 11 (Day 11)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:00:21
User entered '23 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

FDA-CBER-2022-1614-0712789

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:05:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:22
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:14
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:00:47
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:31
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:47:27
User entered empty.	System	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:33
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:05:36
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:35
Query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:21
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User opened query 'The symptom log is not completed for this date. Please confirm if "not done" should be selected for all symptoms in this log. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:00:31
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

FDA-CBER-2022-1614-0712795

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:40
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:43
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

FDA-CBER-2022-1614-0712800

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:48
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:52
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:57
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:05:59
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:11:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:47:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:10:27
Signature has been broken.		22 Apr 2021 07:10:27
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:10:27
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:22:02
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:01:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:18:29
Query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:14:07
User opened query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:05:01
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 12 (Day 12)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:03:14
User entered '24 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:06:42
DataPoint Verified.		05 Nov 2020 17:06:40
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:14
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:03:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:44
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:48:10
User entered empty.	System	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:46
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Symptom log was not completed on this day. Please confirm if the answer can be "not done" or "blank"' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:06:50
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:48
Query 'Symptom log was not completed on this day. Please confirm if the answer can be "not done" or "blank"' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User opened query 'Symptom log was not completed on this day. Please confirm if the answer can be "not done" or "blank"' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:04:08
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:53
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:55
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

FDA-CBER-2022-1614-0712820

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:06:58
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:00
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

FDA-CBER-2022-1614-0712822

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:04
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:05
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:07
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:10
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:12
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:14
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:11:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:13:55
Signature has been broken.		22 Apr 2021 07:13:55
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:13:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:07:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:01
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:02:16

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:11:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:18:41
Query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:15:14
User opened query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:05:22
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 13 (Day 13)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:04:44
User entered '25 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Please review if "assessment not done" should be checked' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:07:59
DataPoint Verified.		05 Nov 2020 17:07:47
Query 'Please review if "assessment not done" should be checked' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:24:33
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User opened query 'Please review if "assessment not done" should be checked' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:05:03
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:01
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:48:56
User entered empty.	System	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:27
User closed query 'As symptom log was not completed, please review if "not done" or "blank" should be completed. ' (Site from CRA).		05 Nov 2020 17:08:22
Query 'As symptom log was not completed, please review if "not done" or "blank" should be completed. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:24:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User opened query 'As symptom log was not completed, please review if "not done" or "blank" should be completed. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:05:55
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

FDA-CBER-2022-1614-0712839

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

FDA-CBER-2022-1614-0712840

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:32
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:11:52

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:11:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:11:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:11:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:47
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:51
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:11:52
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:04
Signature has been broken.		22 Apr 2021 07:15:04
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:04
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:08:53
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:23:56
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:04:03

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:18:51
Query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:16:06
User opened query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:05:55
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 14 (Day 14)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:33
User entered '26 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:09:39
DataPoint Verified.		05 Nov 2020 17:09:36
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:18
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:06:49
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:11:52

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:41
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:49:36
User entered empty.	System	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:42
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:47
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' (Site from CRA).		05 Nov 2020 17:09:44
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:07:16
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

FDA-CBER-2022-1614-0712860

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:49
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:11:52

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:50
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:11:52

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:52
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:54
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

FDA-CBER-2022-1614-0712864

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:11:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:57
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

FDA-CBER-2022-1614-0712866

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:11:52

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:09:59
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:02
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:04
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:05
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:11:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:07
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:09
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:10
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:13
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:11:52
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:15:54
Signature has been broken.		22 Apr 2021 07:15:54
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:15:54
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:10:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:25:11
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:05:38

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:11:52
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 15 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:19:03
Query 'Per CDM: Please verify that Symptom Log Line 15 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:16:53
User opened query 'Per CDM: Please verify that Symptom Log Line 15 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:07:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 15 (Day 15)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:08:00
User entered '27 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:18
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).		05 Nov 2020 17:11:08
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:45
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:08:12
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:50:19
User entered empty.	System	21 Oct 2020 19:06:57

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:21
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:57:06
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 04:14:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 04:14:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:23
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' (Site from CRA).		05 Nov 2020 17:11:09
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:44
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:08:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

FDA-CBER-2022-1614-0712883

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

FDA-CBER-2022-1614-0712892

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:48
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:11:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:16:48
Signature has been broken.		22 Apr 2021 07:16:48
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:16:48
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:11:50
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 14:36:36
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:06:57

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 16 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:19:26
Query 'Per CDM: Please verify that Symptom Log Line 16 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:17:39
User opened query 'Per CDM: Please verify that Symptom Log Line 16 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:07:20
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 16 (Day 16)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:09:51
User entered '28 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:06
User closed query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).		05 Nov 2020 17:12:59
Query 'Please confirm if "assessment not done" should be checked. ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:30
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User opened query 'Please confirm if "assessment not done" should be checked. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:03
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:08
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:51:01
User entered empty.	System	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:10
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:12
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:57:17
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 04:14:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 04:14:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:15
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options.' (Site from CRA).		05 Nov 2020 17:13:13
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options.' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:33
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:13
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:27
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

FDA-CBER-2022-1614-0712914

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

FDA-CBER-2022-1614-0712916

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

FDA-CBER-2022-1614-0712917

US3252075

Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:11:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:17:34
Signature has been broken.		22 Apr 2021 07:17:34
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:17:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:01:26
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:09:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 17 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:19:45
Query 'Per CDM: Please verify that Symptom Log Line 17 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:18:32
User opened query 'Per CDM: Please verify that Symptom Log Line 17 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:07:45
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 17 (Day 17)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:39
User entered '29 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:17:04
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:16:58
Query 'Please confirm if "assessment not done" should be checked. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:25:06
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User opened query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:54
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:06
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:51:45
User entered empty.	System	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:07
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

FDA-CBER-2022-1614-0712925

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:57:39
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 04:14:56
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	30 Nov 2020 04:14:56
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:17:19
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:17
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:25:04
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:46
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:15
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:27
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

FDA-CBER-2022-1614-0712934

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:35
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:37
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

FDA-CBER-2022-1614-0712937

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:40
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:42
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:11:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:18:28
Signature has been broken.		22 Apr 2021 07:18:28
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:18:28
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:17:44
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:24:57
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:10:10

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 18 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:20:22
Query 'Per CDM: Please verify that Symptom Log Line 18 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:20:39
User opened query 'Per CDM: Please verify that Symptom Log Line 18 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:08:19
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 18 (Day 18)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:11:58
User entered '30 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:11:52

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:18:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:05
Query 'Please confirm if "assessment not done" should be checked. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:28
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User opened query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:12:10
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:11:52

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:12
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:52:27
User entered empty.	System	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:11:52

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:10
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:17
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).		05 Nov 2020 17:18:15
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:12:19
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:11:52

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:19
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:11:52

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:21
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:24
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:45
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:43
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

FDA-CBER-2022-1614-0712956

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:40
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:11:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:52:27
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:20:35
Signature has been broken.		22 Apr 2021 07:20:35
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:20:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:26:20
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:11:21

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User closed query 'Per CDM: Please verify that Symptom Log Line 19 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 10:21:09
Query 'Per CDM: Please verify that Symptom Log Line 19 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'updated as per query' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:26:11
User opened query 'Per CDM: Please verify that Symptom Log Line 19 in Covid-19 Assessment 13 Aug 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:08:35
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'Day 19 (Day 19)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
DataPoint Verified.		26 Apr 2021 20:57:14
DataPoint Un-verified.		23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:14:36
User entered '31 Aug 2020'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:11:52

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered '0' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:00
User closed query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).		05 Nov 2020 17:18:57
Query 'Please confirm if "assessment not done" should be checked. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:31
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User opened query 'Please confirm if "assessment not done" should be checked. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:14:56
User entered '0'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:02
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User entered '%'	System	26 Apr 2021 20:53:08
User entered empty.	System	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:03
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 03:51:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:05
Query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' answered with 'this has been completed. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User opened query 'Symptom log was not completed for this date, please review and consider if "not done" or "blank" are options. ? ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:14:47
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:20
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:22
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:25
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:11:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:26
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:11:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:28
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:29
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

FDA-CBER-2022-1614-0712977

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:31
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:33
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:11:52

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:34
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:36
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:38
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:39
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

FDA-CBER-2022-1614-0712983

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:11:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:41
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:44
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:33:45
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 20:57:14
Signature has been broken.	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
User entered 'None (None)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	26 Apr 2021 20:53:08
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 21:15:57
DataPoint Verified.		23 Apr 2021 18:21:31
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 07:26:06
Signature has been broken.		22 Apr 2021 07:26:06
User entered empty; reason for change Data Entry Error		22 Apr 2021 07:26:06
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:19:43
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 15:27:23
User entered 'None (None)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 19:12:14

FDA-CBER-2022-1614-0712985

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:52

Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:19
User entered '13 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:56:38
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:52

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 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:37
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	17 Aug 2020 16:38:19
	(b) (4)	

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:52

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 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
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)	28 Oct 2020 19:32:37
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:48
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 'Done' (Site from System).	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 19:03:35
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	17 Aug 2020 16:38:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:52

Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:56
User entered '13 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:56:38
User entered '07 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:11:52
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:46:58
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:11:52
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:59:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:11:52

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 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:59:38
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	17 Sep 2020 19:05:19
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	24 Aug 2020 21:15:30
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	24 Aug 2020 21:15:30
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:54:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:11:52

Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:59:40
User entered empty.	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:52

CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:51
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:59:41
User entered empty; reason for change Data Entry Error	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 19:05:19
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:38:19

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:11:52

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:51
Amendment Manager: User entered '1'	System	21 Aug 2020 02:54:48
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:54:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per DM CLR: Please note that there is no corresponding AE recorded for this Covid19 Assessment data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:58:43
Query 'Per DM CLR: Please note that there is no corresponding AE recorded for this Covid19 Assessment data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' answered with 'AE has been reactivated ' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:30:03
User opened query 'Per DM CLR: Please note that there is no corresponding AE recorded for this Covid19 Assessment data. Please reconcile and update to record the AE as applicable, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:03:46
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:32:55
Query 'Covid-19 Severity Assessment is not noted in source. Please review. ' canceled (Site from CRA).		27 Oct 2020 19:32:49
User opened query 'Covid-19 Severity Assessment is not noted in source. Please review. ' (Site from CRA)		23 Oct 2020 17:21:54
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:10
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

FDA-CBER-2022-1614-0712997

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:12
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:14
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52

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 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:15
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:53
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

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 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:50
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:49
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:47
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52

Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:45
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:43
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:42
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:40
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:38
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:37
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:19
User closed query ' Per CDM: it appears that 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:25:09
Query ' Per CDM: it appears that 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No yet data is present. Please review and reconcile.' answered with 'no information about ARDS' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 06:25:47
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 06:25:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 06:25:07
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 06:25:07
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 06:24:00
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 06:24:00
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 06:24:00
User opened query ' Per CDM: it appears that 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is recorded as No yet data is present. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	03 Jan 2021 06:32:27
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:34
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:35:32
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:26
User closed query 'Per CDM: 'Did the subject have Respiratory failure?' and/or 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are 'NO'? yet response is provided for High-Flow Oxygen? Please review/update accordingly. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:43:55
Query 'Per CDM: 'Did the subject have Respiratory failure?' and/or 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are 'NO'? yet response is provided for High-Flow Oxygen? Please review/update accordingly. Thank you ' answered with 'response removed' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 05:50:21
DataPoint Un-verified.	(b) (4), (b) (6)	18 Feb 2021 05:50:10
User entered empty; reason for change Data Entry Error		18 Feb 2021 05:50:10
User opened query 'Per CDM: 'Did the subject have Respiratory failure?' and/or 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' are 'NO'? yet response is provided for High-Flow Oxygen? Please review/update accordingly. Thank you ' (Site from DM).		12 Feb 2021 12:24:58
User closed query 'Source page (12) is missing, unable to verify. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:27:12
DataPoint Verified.		05 Nov 2020 17:27:07
Query 'Source page (12) is missing, unable to verify. ' answered with 'this has been uploaded to EMR.' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:37:04
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:36:53
User opened query 'Source page (12) is missing, unable to verify. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:59:13
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:18
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:20
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

FDA-CBER-2022-1614-0713018

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52

Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:22
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:23
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:25
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:26
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:28
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:29
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:31
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:32
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:34
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:30
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:24
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:22
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:21
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:19
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:17
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:16
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:14
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:12
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:11
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:09
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:07
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:18:46
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:57:08
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:57:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:05
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:04
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

FDA-CBER-2022-1614-0713041

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:02
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:01
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075

Folder: Covid-19 Assessment 13 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:11:52

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 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:28:59
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

FDA-CBER-2022-1614-0713044

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:28:58
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

Folder: Covid-19 Assessment 13 Aug 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:11:52
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:36:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:28:56
User entered empty.	Joanna Gurrola Mahoney (b) (4)	19 Oct 2020 19:57:45

US3252075
Folder: Covid-19 Assessment 13 Aug 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:11:52
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:37:01
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:40:51
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 15:21:04
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 16:03:06

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:11:52

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:11:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:32:34
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:32:40
User entered '15 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:11:52

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:11:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:33:15
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 17AUG2020, 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)	01 Mar 2021 22:19:39
Query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 17AUG2020, 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 'As per PPD Central lab, results have been uploaded and all saliva samples were collected' (Site from DM).	mathew maran (b) (4) (b) (4)	01 Mar 2021 10:10:51
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 5, EDC Sample date is 17AUG2020, 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 05:17:39
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 12:49:00
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 numbers for saliva day 5-21 is 1F623698532, 1F616894700, 1F619517540, 1F623185516, 1F600586978. AWB is 906907881545 and 906907881512.' (Site from DM).	mathew maran (b) (4) (b) (4)	11 Feb 2021 03:51:13
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 07:31:14

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17AUG2020 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 07:31:14
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17AUG2020 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 11:48:34
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17AUG2020 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 02:58:15
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17,19,21,26AUG2020 and 02SEP2020 is recorded under Illness Visit Day 5,7,9,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 02:57:55
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17,19,21,26AUG2020 and 02SEP2020 is recorded under Illness Visit Day 5,7,9,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:20:35
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:33:21
User entered '17 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:11:52

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:11:52
Was Saliva Collected?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva Re-Query : For Day 7, EDC Sample date is 19AUG2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F616894700) is reported. Please note that the collection date in edc and PPD should be same. Hence please confirm the correct date to be updated in the PPD central lab for Day 7.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:38:30
Query 'Per GCL Lab Reconciliation: Saliva Re-Query : For Day 7, EDC Sample date is 19AUG2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F616894700) is reported. Please note that the collection date in edc and PPD should be same. Hence please confirm the correct date to be updated in the PPD central lab for Day 7.' answered with 'the samples of Day 9, Day 7 Day 21 & Day 14 have sent together to the central lab with the draw date of 15-Aug-2020 on the requisition form, but per source the collection date of the Day 7 saliva sample is correct as entered. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:26:37
User opened query 'Per GCL Lab Reconciliation: Saliva Re-Query : For Day 7, EDC Sample date is 19AUG2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F616894700) is reported. Please note that the collection date in edc and PPD should be same. Hence please confirm the correct date to be updated in the PPD central lab for Day 7.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:39:44
User closed query ' Per GCL Lab Reconciliation: Saliva : Sample dated 19AUG2020 for Day 7 in EDC, however 15AUG2020 is reported under Day7((Accession # 1F600114796) in PPD Central lab. Please confirm date of collection for Day 7 and update EDC or PPD Central lab' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:37:56
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:11:52

Was Saliva Collected?

Audit	User	Time (GMT)
Query ' Per GCL Lab Reconciliation: Saliva : Sample dated 19AUG2020 for Day 7 in EDC, however 15AUG2020 is reported under Day7((Accession # 1F600114796) in PPD Central lab. Please confirm date of collection for Day 7 and update EDC or PPD Central lab' answered with 'other samples have been shipped out and received at PPD on 25AUG2020. AWB number 906907881512' (Site from DM).	mathew maran (b) (4) (b) (4)	05 Mar 2021 07:57:36
User opened query ' Per GCL Lab Reconciliation: Saliva : Sample dated 19AUG2020 for Day 7 in EDC, however 15AUG2020 is reported under Day7((Accession # 1F600114796) in PPD Central lab. Please confirm date of collection for Day 7 and update EDC or PPD Central lab' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:55:01
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 19AUG2020 for Day 7 in EDC, however 15AUG2020 is reported under Day7((Accession # 1F600114796) in PPD Central lab. Please confirm date of collection for Day 3 and update EDC or PPD Central lab.' canceled (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:54:37
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 19AUG2020 for Day 7 in EDC, however 15AUG2020 is reported under Day7((Accession # 1F600114796) in PPD Central lab. Please confirm date of collection for Day 3 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:54:30
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:33:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:11:52
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 19AUG2020 for Day 7 in EDC, however 15AUG2020 is reported under Day7((Accession # 1F600114796) in PPD Central lab. Please confirm date of collection for Day 3 and update EDC or PPD Central lab.' canceled (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:54:41
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 19AUG2020 for Day 7 in EDC, however 15AUG2020 is reported under Day7((Accession # 1F600114796) in PPD Central lab. Please confirm date of collection for Day 3 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:54:23
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.' canceled (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:49:30
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 07:31:20
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19AUG2020 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 07:31:20
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19AUG2020 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 11:48:42
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19AUG2020 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 02:58:37

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:33:49
User entered '19 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:11:52

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:11:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:34:08
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:38:40
Query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' answered with 'the samples of Day 9, Day 7 Day 21 & Day 14 have sent together to the central lab with the draw date of 15-Aug-2020 on the requisition form, but per source, the collection date of the Day 9 saliva sample is correct as entered. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:30:26
User opened query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:06:17
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 21AUG2020 for Day 9 in EDC, however 15AUG2020 is reported under Day9((Accession # 1F619517540) in PPD Central lab. Please confirm date of collection for Day 9 and update EDC or PPD Central lab' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:06:17
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 21AUG2020 for Day 9 in EDC, however 15AUG2020 is reported under Day9((Accession # 1F619517540) in PPD Central lab. Please confirm date of collection for Day 9 and update EDC or PPD Central lab' answered with 'other samples have been shipped out and received at PPD on 25AUG2020. AWB number 906907881512' (Site from DM).	mathew maran (b) (4) (b) (4)	05 Mar 2021 07:57:46

US3252075
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:11:52
Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 21AUG2020 for Day 9 in EDC, however 15AUG2020 is reported under Day9((Accession # 1F619517540) in PPD Central lab. Please confirm date of collection for Day 9 and update EDC or PPD Central lab' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:57:02
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 12:47:12
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: 1F64203' (Site from DM).	mathew maran (b) (4) (b) (4)	03 Mar 2021 05:56:06
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 07:31:25
User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 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 07:31:25
Query 'Per GCL LAB reconciliation: Saliva: Day 9 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 'task has been sent to source' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	25 Jan 2021 11:48:50
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 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 02:58:57
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:34:15

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:11:52

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:11:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:34:42
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:38:44
Query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' answered with 'the samples of Day 9, Day 7 Day 21 & Day 14 have sent together to the central lab with the draw date of 15-Aug-2020 on the requisition form, but per source, the collection date of the Day 14 saliva sample is correct as entered. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:30:44
User opened query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:06:25
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 26AUG2020 for Day 14 in EDC, however 15AUG2020 is reported under Day14((Accession # 1F619517540) in PPD Central lab. Please confirm date of collection for Day 14 and update EDC or PPD Central lab' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:06:25
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 26AUG2020 for Day 14 in EDC, however 15AUG2020 is reported under Day14((Accession # 1F619517540) in PPD Central lab. Please confirm date of collection for Day 14 and update EDC or PPD Central lab' answered with 'other samples have been shipped out and received at PPD on 25AUG2020. AWB number 906907881512' (Site from DM).	mathew maran (b) (4) (b) (4)	05 Mar 2021 07:57:52

US3252075
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:11:52
Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 26AUG2020 for Day 14 in EDC, however 15AUG2020 is reported under Day14((Accession # 1F619517540) in PPD Central lab. Please confirm date of collection for Day 14 and update EDC or PPD Central lab' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:57:33
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 12:48:21
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 'All saliva samples have been shipped out since 25AUG2020 with tracking number 906907881512. Reports were received on 01SEP2020' (Site from DM).	mathew maran (b) (4) (b) (4)	03 Mar 2021 06:08:12
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 07:31:31
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 26AUG2020 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 07:31:31
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 26AUG2020 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 11:48:57

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 26AUG2020 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 02:59:22
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:34:43
User entered '26 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:11:52

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:11:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:05
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 22:54:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 22:54:30
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:34:28
User closed query 'Please review and consider answering "No" to the question. ' (Site from CRA).		11 Nov 2020 17:34:26
Query 'Please review and consider answering "No" to the question. ' answered with 'Updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:21:31
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:21:24
User opened query 'Please review and consider answering "No" to the question. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:33:41
User closed query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' (Site from CRA).		05 Nov 2020 17:33:41
Query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' answered with 'per query not done is not an option, does NA suffice? ' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	31 Oct 2020 02:10:06
User opened query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:57:44
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 19:57:01
DataPoint Verified.		23 Oct 2020 16:35:13
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 19:21:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 19:21:43
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 19:21:43

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:11:52

Was Saliva Collected?

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 15:09:35
User entered empty.	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:11:52
Date of Collection

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:38:48
Query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' answered with 'the samples of Day 9, Day 7 Day 21 & Day 14 have sent together to the central lab with the draw date of 15-Aug-2020 on the requisition form, but per source the collection date of the Day 7 saliva sample is correct as entered. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:31:06
User opened query 'Per GCL Lab Reconciliation: Saliva Re-query : Please update the actual sample collection date in preclarus portal to reflect same with EDC data. Please note sample collection date must be same in both EDC and Preclarus and respond to the query once updated.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:06:33
User closed query 'Per GCL Lab Reconciliation: Saliva : For Day 21, EDC Sample date is 02SEP2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F600586978) is reported. Hence please confirm correct date of collection for Day 21 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:06:33
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Per GCL Lab Reconciliation: Saliva : For Day 21, EDC Sample date is 02SEP2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F600586978) is reported. Hence please confirm correct date of collection for Day 21 and update EDC or PPD Central lab.' answered with 'Sample day 21 1F600586978 and all other samples have been shipped out and received at PPD on 25AUG2020. AWB number 906907881512' (Site from DM).	mathew maran (b) (4) (b) (4)	05 Mar 2021 07:56:50

US3252075
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:11:52
Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva : For Day 21, EDC Sample date is 02SEP2020, however in PPD Central Lab sample dated 15AUG2020 (Accession # 1F600586978) is reported. Hence please confirm correct date of collection for Day 21 and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 14:01:07
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 12:48:27
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 'All saliva samples have been shipped out since 25AUG2020 with tracking number 906907881512. Reports were received on 01SEP2020' (Site from DM).	mathew maran (b) (4) (b) (4)	03 Mar 2021 06:08:19
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 07:31:36
User closed query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 02SEP2020 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 07:31:36
Query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 02SEP2020 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 11:49:04

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 02SEP2020 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 02:59:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:06
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 22:54:30
User entered '02 Sep 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 22:54:30
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:35:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:11:52

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:11:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Please review and consider answering "No" to the question. ? ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 17:34:34
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:34:33
Query 'Please review and consider answering "No" to the question. ? ' answered with 'Updated' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:21:45
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:21:38
User opened query 'Please review and consider answering "No" to the question. ? ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:34:20
User closed query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:34:20
Query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' answered with 'per qiuery not done is not an option. please confirm if NA suffices ' (Site from CRA).	Shannon Moyer (b) (4) (b) (4)	31 Oct 2020 02:10:50
User opened query 'Per protocol, saliva sample should have been collected on this date. Please confirm if you can select "not done" for this question' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 19:57:55
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 19:57:49
DataPoint Verified.		23 Oct 2020 16:35:17
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 19:21:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 19:21:43
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 19:21:43
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 15:09:35
User entered empty.	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:35:19
User entered empty.	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 15:09:35

US3252075
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:22
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:46:49

US3252075
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:23
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:46:49

US3252075

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

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 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:25
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:46:49

FDA-CBER-2022-1614-0713081

US3252075
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User entered 'SICKD1'	System	17 Aug 2020 16:46:49

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:39
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:41
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:46
User entered '16:50'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User entered '13 Aug 2020 16:50'	System	17 Aug 2020 16:47:50

US3252075
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:13:58
User entered '65' in	Shannon Moyer (b) (4)	17 Aug 2020 16:47:50
	(b) (4)	
DataPoint set to visible.	System	17 Aug 2020 16:46:49

US3252075
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:01
User entered '165.0' lb	Shannon Moyer (b) (4)	17 Aug 2020 16:47:50
	(b) (4)	
DataPoint set to visible.	System	17 Aug 2020 16:46:49

US3252075
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:10
User entered '98.7' F	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:17
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	17 Aug 2020 16:47:50
	(b) (4)	

FDA-CBER-2022-1614-0713090

US3252075
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:21
User entered empty.	Shannon Moyer (b) (4)	17 Aug 2020 16:47:50
	(b) (4)	

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:31
User entered '73'	Shannon Moyer (b) (4)	17 Aug 2020 16:47:50
	(b) (4)	

US3252075
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User entered 'bpm'	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:45
User entered '16'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User entered 'breaths/min'	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Requery: Please indicate if CS or NCS' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:03:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:14:55
Query 'Requery: Please indicate if CS or NCS' answered with 'NCS' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:33:41
User opened query 'Requery: Please indicate if CS or NCS' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:22:09
User closed query 'Re-query: Per CDM, below response does not confirm if CS/NCS. Please indicate if CS/NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 18:22:09
Query 'Re-query: Per CDM, below response does not confirm if CS/NCS. Please indicate if CS/NCS and report as AE, if appropriate. ' answered with 'Vital signs updated' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	15 Sep 2020 13:11:40
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 12:34:49
User opened query 'Re-query: Per CDM, below response does not confirm if CS/NCS. Please indicate if CS/NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Aug 2020 18:10:40
Un-reviewed for Data Management.	(b) (4), (b) (6)	18 Aug 2020 18:09:26
Reviewed for Data Management.	(b) (4), (b) (6)	18 Aug 2020 18:09:18
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI, Recommendation a low salt diet and monitoring of blood pressure and to follow up with PMD ' (Site from System).	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 17:07:57
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User entered '162'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User entered 'mmHg'	System	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:15:22
User entered '85'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:47:50

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User entered 'mmHg'	System	17 Aug 2020 16:47:50

US3252075
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00

US3252075

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00

US3252075

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:15:37
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:50:17

US3252075

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:15:39
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	17 Aug 2020 16:50:17
	(b) (4)	

US3252075

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:11:52

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 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:18:16
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:50:35

US3252075

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:00
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:18:17
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	17 Aug 2020 16:50:35

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:48
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:18

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:48
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:18

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:48
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:18

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Folder OID

Audit	User	Time (GMT)
User entered 'SICKD28'	System	21 Oct 2020 16:33:18

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:52
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:25

US3252075
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 16:33:25

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:56
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:35

US3252075

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:19:56
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:35

US3252075

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:20:00
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:41

FDA-CBER-2022-1614-0713128

US3252075

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:11:52

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:20:00
User entered empty.	Joanna Gurrola Mahoney (b) (4)	21 Oct 2020 16:33:41

US3252075

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

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:50:26

US3252075

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

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:50:26

US3252075

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

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:48:35
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Mar 2021 04:50:26

US3252075

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

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'UNBLND_DECIDE'	System	10 Mar 2021 04:50:26

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 19:35:58
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered empty.	System	10 Mar 2021 04:50:49

US3252075

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

Form: Unblinding

Generated On: 11 Aug 2021 22:11:52

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered '1'	System	10 Mar 2021 04:50:49

US3252075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:52:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered empty.	System	10 Mar 2021 04:52:15
DataPoint set to visible.	System	10 Mar 2021 04:50:49

US3252075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:52:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered empty.	System	10 Mar 2021 04:52:15
DataPoint set to visible.	System	10 Mar 2021 04:50:49

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '10:55'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered '9 Mar 2021 10:55'	System	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '98.9' F	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '73'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'bpm'	System	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '16'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'breaths/min'	System	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '133'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'mmHg'	System	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '72'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'mmHg'	System	10 Mar 2021 04:52:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:11:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Mar 2021 04:52:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered empty.	System	10 Mar 2021 04:52:15
DataPoint set to visible.	System	10 Mar 2021 04:50:49

FDA-CBER-2022-1614-0713169

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '11:46'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered '9 Mar 2021 11:46'	System	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '97.8' F	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '70'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'bpm'	System	10 Mar 2021 04:52:15

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '16'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'breaths/min'	System	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '161'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'mmHg'	System	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:17
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '83'	(b) (4), (b) (6)	10 Mar 2021 04:52:15

US3252075

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:11:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'mmHg'	System	10 Mar 2021 04:52:15

US3252075

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:37
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 04:52:28

US3252075

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:50:37
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:52:28

US3252075

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:30:02
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:52:44

US3252075

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:30:02
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:52:44

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:30:02
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 04:52:44

US3252075

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'mRNA-1273'	System	10 Mar 2021 04:52:44
DataPoint set to visible.	System	10 Mar 2021 04:50:49

US3252075

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:30:02
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:30:02
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '11:13'	(b) (4), (b) (6)	10 Mar 2021 04:52:44

US3252075

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered '9 Mar 2021 11:13'	System	10 Mar 2021 04:52:44

US3252075

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:30:02
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Mar 2021 04:52:44

US3252075

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:30:02
User entered 'ONCE'	System	10 Mar 2021 04:52:44

US3252075

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

Form: Exposure

Generated On: 11 Aug 2021 22:11:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 04:52:44

US3252075

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:52:56

US3252075

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:52:56

US3252075

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:43
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '10:57'	(b) (4), (b) (6)	10 Mar 2021 04:52:56

FDA-CBER-2022-1614-0713200

US3252075

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered '9 Mar 2021 10:57'	System	10 Mar 2021 04:52:56

US3252075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:11:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:48
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:53:07

US3252075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:48
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '9 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 04:53:07

US3252075

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:48
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '10:57'	(b) (4), (b) (6)	10 Mar 2021 04:53:07

FDA-CBER-2022-1614-0713204

US3252075

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:11:52

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered '9 Mar 2021 10:57'	System	10 Mar 2021 04:53:07

US3252075

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

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:52:52
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 04:53:18

US3252075

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

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:00:57
User entered '1'	System	10 Mar 2021 04:53:18

US3252075
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:11:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:07:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 03:25:46

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:07:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered '16 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 03:25:46

FDA-CBER-2022-1614-0713209

US3252075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:07:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Mar 2021 03:25:46

US3252075

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:11:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:07:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 03:25:46

US3252075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:07:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:53:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 03:25:54

US3252075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:07:44
User entered '1'	System	17 Mar 2021 03:25:54

US3252075

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:11:52

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:07:44
User entered '1'	System	17 Mar 2021 03:25:54
DataPoint set to visible.	System	17 Mar 2021 03:25:54

Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 02:48:43

US3252075
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered '9 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 02:48:43

US3252075

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓(b) (4)▓	22 Apr 2021 18:45:32
User entered 'Clinic (Clinic)'	▓(b) (4), (b) (6)▓	12 Apr 2021 02:48:43

US3252075
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:11:52
Folder OID

Audit	User	Time (GMT)
User entered 'OLD29'	System	12 Apr 2021 02:48:43

FDA-CBER-2022-1614-0713218

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 02:49:15

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered '9 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 02:49:15

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered '07:26'	(b) (4), (b) (6)	12 Apr 2021 02:49:15

US3252075
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '9 Apr 2021 07:26'	System	12 Apr 2021 02:49:15

Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered '98.1' F	(b) (4), (b) (6)	12 Apr 2021 02:49:15

Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Apr 2021 02:49:15

FDA-CBER-2022-1614-0713224

US3252075
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓(b) (4)▓	22 Apr 2021 18:45:32
User entered empty.	▓(b) (4), (b) (6)▓	12 Apr 2021 02:49:15

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered '62'	(b) (4), (b) (6)	12 Apr 2021 02:49:15

US3252075
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 02:49:15

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered '16'	(b) (4), (b) (6)	12 Apr 2021 02:49:15

US3252075
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 02:49:15

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered '164'	(b) (4), (b) (6)	12 Apr 2021 02:49:15

Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 02:49:15

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered '88'	(b) (4), (b) (6)	12 Apr 2021 02:49:15

US3252075
Folder: OL-D29 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:11:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 02:49:15

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 02:58:25
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 02:49:21

US3252075

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:11:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▊(b) (4)▊	22 Apr 2021 18:45:32
User entered '9 Apr 2021' reason for change: Data Entry Error	▊(b) (4), (b) (6)▊	12 Apr 2021 02:58:25
User entered empty.	▊(b) (4), (b) (6)▊	12 Apr 2021 02:49:21

Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 18:45:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 02:59:48

US3252075

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓▓(b) (4)	22 Apr 2021 18:45:32
User entered '9 Apr 2021'	▓▓(b) (4), (b) (6)▓▓	12 Apr 2021 02:59:48

US3252075

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓▓(b) (4)▓▓	22 Apr 2021 18:45:32
User entered '09:45' reason for change: New Information	▓▓(b) (4), (b) (6)▓▓	13 Apr 2021 02:51:12
User entered '07:40'	▓▓(b) (4), (b) (6)▓▓	12 Apr 2021 02:59:48

US3252075

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:11:52

Collection date and time (derived)

Audit	User	Time (GMT)
User entered '9 Apr 2021 09:45'	System	13 Apr 2021 02:51:12
User entered '9 Apr 2021 07:40'	System	12 Apr 2021 02:59:48

US3252075
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:11:52
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:48:53
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:33:33
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse event recorded corresponding page. Please review and update accordingly. else clarify' answered with 'updated ' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	12 Oct 2020 03:07:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	12 Oct 2020 03:07:32
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events recorded corresponding page. Please review and update accordingly. else clarify' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:57:58
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	28 Sep 2020 01:35:59
User closed query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response. ' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:42:49

US3252075
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:11:52

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response. ' answered with 'corrected' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 17:48:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 17:47:46
User opened query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response. ' (Site from Safety).	(b) (4), (b) (6)	21 Aug 2020 16:50:07
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:43:54

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

AEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:35
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:47:03
User entered 'USA-US108-2020-mRNA-1273-P301000001'	System	25 Aug 2020 14:46:52
User entered 'New'	(b) (4), (b) (6)	25 Aug 2020 14:46:52

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:32
User closed query 'Per CDM: per sponsor review, please consider updating this to COVID-19' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:12:08
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)	17 Nov 2020 05:30:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 05:30:52
Query 'Per CDM: per sponsor review, please consider updating this to COVID-19' answered with 'Updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:29:59
Data point term sent to Coder	System	17 Nov 2020 05:29:52
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:29:42
Coding entries removed.	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:29:42
User entered 'COVID-19' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:29:42
User opened query 'Per CDM: per sponsor review, please consider updating this to COVID-19' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 13:45:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:14
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 07:21:27
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 07:21:27
Data point term sent to Coder	System	09 Nov 2020 07:20:20
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 07:19:34

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Adverse event

Audit	User	Time (GMT)
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 07:19:34
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:19:23
Coding entries removed.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:19:23
User entered 'COVID-19 infection' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 07:19:23
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 18:24:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:41:38
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)	03 Nov 2020 19:28:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 19:28:30
Data point term sent to Coder	System	03 Nov 2020 19:27:54
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
Data point term sent to Coder	System	14 Oct 2020 05:15:30
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
Query 'PV Query: Please provide results of COVID-19 test performed on 13 Aug 2020.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:53:53
Query 'PV Query: Please provide the date the COVID-19 test performed on 07 Aug 2020 resulted.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:53:50
User opened query 'PV Query: Please provide results of COVID-19 test performed on 13 Aug 2020.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:59:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Adverse event

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the date the COVID-19 test performed on 07 Aug 2020 resulted.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:59:33
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)	15 Sep 2020 14:19:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 14:19:46
Data point term sent to Coder	System	15 Sep 2020 14:19:13
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:19:11
User entered 'COVID-19 POSITIVE' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:19:11
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)	24 Aug 2020 20:06:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 20:06:43
Data point term sent to Coder	System	24 Aug 2020 19:08:44
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:41:45
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:43:30
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:45
User closed query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 15:59:15
Query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' answered with 'this has been updated.' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:29:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:43
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User opened query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:58:54
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Aug 2020 21:17:31
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:44
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 17:48:18
User closed query 'Per CDM: Corresponding Con Meds (#1-4) start date is recorded as '13-AUG-2020'? Please review and reconcile Con Med and AE start dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:40:46
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:50:31
Query 'Per CDM: Corresponding Con Meds (#1-4) start date is recorded as '13-AUG-2020'? Please review and reconcile Con Med and AE start dates as appropriate else clarify.' answered with 'Date has been updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:01:58
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:00:27
User opened query 'Per CDM: Corresponding Con Meds (#1-4) start date is recorded as '13-AUG-2020'? Please review and reconcile Con Med and AE start dates as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:52:00
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User closed query 'PV Query: Please confirm if the subject first began exhibiting symptoms of COVID-19 on 13 Aug 2020. If not, please consider updating event start date to onset of symptoms.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:39:40
Query 'PV Query: Please confirm if the subject first began exhibiting symptoms of COVID-19 on 13 Aug 2020. If not, please consider updating event start date to onset of symptoms.' answered with 'Done per source' (Site from Safety).	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:19:33
User entered '07 Aug 2020' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:19:11

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject first began exhibiting symptoms of COVID-19 on 13 Aug 2020. If not, please consider updating event start date to onset of symptoms.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 17:51:36
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:29:56
User closed query 'Per source, start time is 12:54. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:44:36
Query 'Per source, start time is 12:54. Please review and reconcile. ' answered with 'No time on AE. ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 22:51:41
User closed query 'Per CDM: Start time of AE 'COVID-19 POSITIVE' is prior to treatment 1 time (07-AUG-2020; 13:37)? Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:40:50
User opened query 'Per source, start time is 12:54. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 20:52:30
DataPoint Un-verified.		08 Nov 2020 20:52:08
DataPoint Verified.		08 Nov 2020 20:51:17
Query 'Per CDM: Start time of AE 'COVID-19 POSITIVE' is prior to treatment 1 time (07-AUG-2020; 13:37)? Please review and update accordingly else clarify.' answered with 'date has been updated' (Site from DM).		06 Nov 2020 20:03:04
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 20:02:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:02:42
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 20:00:27
User opened query 'Per CDM: Start time of AE 'COVID-19 POSITIVE' is prior to treatment 1 time (07-AUG-2020; 13:37)? Please review and update accordingly else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:08:57
Query 'Per CDM: Please note this field is not required, unless start time is within 24 hours of dosing time (07-AUG-2020; 13:37hrs)?. Please review and amend accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:08:48

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note this field is not required, unless start time is within 24 hours of dosing time (07-AUG-2020; 13:37hrs)?. Please review and amend accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:43:29
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 14:19:53
User entered '12:54' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:19:53
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 14:19:11
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 19:09:09
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:09:09
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 19:08:40
User entered '00:00'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 20:02:42
User entered '13 Aug 2020 12:54'	System	06 Nov 2020 20:00:27
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '07 Aug 2020 12:54'	System	15 Sep 2020 14:19:53
User entered empty.	System	24 Aug 2020 19:09:09
User entered '13 Aug 2020 00:00'	System	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:38
DataPoint Un-verified.		08 Nov 2020 20:51:30
DataPoint Verified.		08 Nov 2020 20:51:24
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:19:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:20:45
User closed query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 12:28:07
Query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' answered with 'updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	10 Dec 2020 19:40:33
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	10 Dec 2020 19:40:27
User entered '21 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	10 Dec 2020 19:40:27
User opened query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 23:19:34
User closed query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 15:36:36
Query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' answered with 'updated' (Site from Safety).	Shannon Moyer (b) (4) (b) (4)	23 Nov 2020 09:06:09
User opened query 'PV Query: Please clarify event stop date; stop date should be when all symptoms have resolved. The event end date is reported as 20 Aug 2020; however, symptoms were still reported on that day.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:40:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:40
User closed query 'PV Query: Please consider updating end date as the subject experienced symptoms on 20Aug2020.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:46:16

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating end date as the subject experienced symptoms on 20Aug2020.' answered with 'updated.' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 23:06:14
User entered '20 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 22:51:54
User opened query 'PV Query: Please consider updating end date as the subject experienced symptoms on 20Aug2020.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:38:21
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:39:45
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'End date entered per source' (Site from Safety).	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:21:08
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Sep 2020 14:20:39
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Sep 2020 14:20:39
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Sep 2020 14:19:11
User entered '19 Aug 2020' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:19:11
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Aug 2020 11:39:59

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:31:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:28:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:42
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Nov 2020 20:00:27
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 16:04:30
Query 'Data is required. Please provide.' answered with 'Time is unknown' (Site from System).	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:21:20
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Sep 2020 14:19:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	System	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Severity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:03:56
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:03:42
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:46
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:47
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

FDA-CBER-2022-1614-0713263

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:49
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:52
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:54
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:56
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:31:58
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:32:00
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:32:01
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:32:03
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 18:55:48
User closed query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:42:50
Query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'UPDATED' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	19 Nov 2020 08:08:54
DataPoint Un-verified.	Shannon Moyer (b) (4) (b) (4)	19 Nov 2020 08:08:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Nov 2020 08:08:40
User opened query 'Per CDM: AE started after First Dose, however Relationship to Investigational Product is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:42:41
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:35:12
Query 'Per source, "Not related" please review and reconcile. ' canceled (Site from CRA).		17 Nov 2020 21:35:02
User opened query 'Per source, "Not related" please review and reconcile. ' (Site from CRA).		17 Nov 2020 21:33:01
DataPoint Un-verified.		17 Nov 2020 21:32:31
DataPoint Verified.		17 Nov 2020 21:32:25
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:19:48

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Relationship to investigational product

Audit	User	Time (GMT)
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	17 Sep 2020 16:43:58
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	17 Sep 2020 16:43:58
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 16:43:58
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	24 Aug 2020 19:08:40
User entered 'Not Related (NOT RELATED)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:07:58
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'Not Related (NOT RELATED)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
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)	07 Nov 2020 21:01:02
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 21:01:01
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 'Patient tested positive for COVID-19 during SCR/DAY1 visit. Dosing was discontinued and AE was reported. ' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 20:52:08
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 has been reflected on dosing discontinuation ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:51:28
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 20:51:00
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)	06 Nov 2020 08:16:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:07:29
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:52:09
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:08:44
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:54:37
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:59:06
User entered '1'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:08:58
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:36:59
DataPoint Un-verified.		05 Nov 2020 18:09:08
DataPoint Verified.		05 Nov 2020 18:09:01
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:39:59
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Entered' (Site from Safety).	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:21:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:20:39
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Aug 2020 11:40:31
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:31:48
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:29:43
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:10:17

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Outcome

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 19:10:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:10:17
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 19:08:40
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:35:21
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per DM CLR: SAE Narrative = PATIENT WITH ELEVATED BLOOD PRESSURE X2. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:16:30
Query 'Per DM CLR: SAE Narrative = PATIENT WITH ELEVATED BLOOD PRESSURE X2. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'this should not be recorded as a separate AE. ' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	04 Feb 2021 06:13:50
User opened query 'Per DM CLR: SAE Narrative = PATIENT WITH ELEVATED BLOOD PRESSURE X2. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:09:38
User closed query 'Per DM CLR - RQ: Site's response noted. However, SAE Narrative = TYLENOL 325MG Q4 QD FEVER AND PAIN. However, CM frequency is ONCE DAILY in the CM eCRF. Please review and confirm if this should be QE or QD only? and verify if data should be reconciled with CM eCRF; and if so, update as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:11:05
User closed query 'PV Query: Per COVID-19 Severity Assessment form, the subject displayed evidence of pneumonia. Please describe in the narrative section. If none, please update form accordingly.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 12:28:03
User closed query 'PV Query: The subject's blood pressure was reported as elevated x2. The only reported BP is 162/85 on 13 Aug 2020. Please provide the additional reading.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 12:28:02

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52
Narrative

Audit	User	Time (GMT)
Query 'Per DM CLR - RQ: Site's response noted. However, SAE Narrative = TYLENOL 325MG Q4 QD FEVER AND PAIN. However, CM frequency is ONCE DAILY in the CM eCRF. Please review and confirm if this should be QE or QD only? and verify if data should be reconciled with CM eCRF; and if so, update as appropriate. Otherwise, clarify. ' answered with 'qd is correct.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	10 Dec 2020 19:48:56
Query 'PV Query: The subject's blood pressure was reported as elevated x2. The only reported BP is 162/85 on 13 Aug 2020. Please provide the additional reading.' answered with 'PI meant that the reading was twice the normal range ' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	10 Dec 2020 19:46:16
Query 'PV Query: Per COVID-19 Severity Assessment form, the subject displayed evidence of pneumonia. Please describe in the narrative section. If none, please update form accordingly.' answered with 'patient having evidence of pneumonia is no where on chart and on covid-19 assessment.' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	10 Dec 2020 19:42:32
User opened query 'Per DM CLR - RQ: Site's response noted. However, SAE Narrative = TYLENOL 325MG Q4 QD FEVER AND PAIN. However, CM frequency is ONCE DAILY in the CM eCRF. Please review and confirm if this should be QE or QD only? and verify if data should be reconciled with CM eCRF; and if so, update as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 01:47:45
User opened query 'PV Query: The subject's blood pressure was reported as elevated x2. The only reported BP is 162/85 on 13 Aug 2020. Please provide the additional reading.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 23:19:51
User opened query 'PV Query: Per COVID-19 Severity Assessment form, the subject displayed evidence of pneumonia. Please describe in the narrative section. If none, please update form accordingly.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 23:19:08
User closed query 'PV Query: The subject's blood pressure was reported as elevated x2. The only reported BP is 162/85 on 13 Aug 2020. Please provide the additional reading.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 19:48:50

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Per COVID-19 Severity Assessment form, the subject displayed evidence of pneumonia. Please describe in the narrative section. If none, please update form accordingly.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 19:48:48
User closed query 'Per CDM: Response noted ,SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 21:58:40
Query 'PV Query: The subject's blood pressure was reported as elevated x2. The only reported BP is 162/85 on 13 Aug 2020. Please provide the additional reading.' answered with 'PI meant that the blood pressure of 162/85 was x2, not two separate readings. ' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 17:00:35
Query 'PV Query: Per COVID-19 Severity Assessment form, the subject displayed evidence of pneumonia. Please describe in the narrative section. If none, please update form accordingly.' answered with 'this has been updated as there is not documentation in EMR about pneumonia. ' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:57:40
Query 'Per CDM: Response noted ,SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate.' answered with 'This has updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:55:37
User opened query 'PV Query: The subject's blood pressure was reported as elevated x2. The only reported BP is 162/85 on 13 Aug 2020. Please provide the additional reading.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:40:40
User opened query 'PV Query: Per COVID-19 Severity Assessment form, the subject displayed evidence of pneumonia. Please describe in the narrative section. If none, please update form accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:39:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:38:38

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Narrative

Audit	User	Time (GMT)
User opened query 'Per CDM: Response noted ,SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:23:25
User closed query 'Per DM CLR: SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:23:25
Query 'Per DM CLR: SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate. ' answered with 'Updated.' (Site from DM).	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:33:44
User entered 'SAW PATIENT TODAY AND PATIENT IS SYMPTOMATIC WILL START A BABY ASPIRIN 81 MG QD, ZPAK TAKE AS DIRECTED, CLARITIN 10 MG QD AND TYLENOL 325MG Q4 QD FEVER AND PAIN. PATIENT WITH ELEVATED BLOOD PRESSURE X2, WITH NO DIAGNOSIS OF HYPERTENSION. I RECOMMEND A LOW SALT DIET AND MONITORING OF BLOOD PRESSURE AND TO FOLLOW UP WITH PMD.' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	17 Nov 2020 05:33:32
User closed query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:46:23
User opened query 'Per DM CLR: SAE Narrative = TYLENOL 325MG Q4 PRN. However, in CM eCRF this was given Once Daily. Please review and reconcile AE and CM eCRF pages as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:34:11

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' answered with 'updated. ' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 23:07:50
User entered 'Saw patient today and patient is symptomatic will start a baby aspirin 81 mg QD, ZPAK take as directed, Claritin 10 mg QD and Tylenol 325mg Q4 PRN fever and pain. Patient with elevated blood pressure x2, with no diagnosis of hypertension. I recommend a low salt diet and monitoring of blood pressure and to follow up with PMD.' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	13 Nov 2020 23:07:45
User opened query 'PV Query: Please clarify if the subject was symptomatic when they developed Covid-19 or thereafter. If asymptomatic, please delete this baseline asymptomatic case from EDC. If the subject had symptoms, please complete symptom log on COVID assessment pages in EDC.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:37:47
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
Query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:54:49
User opened query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:59:17
Query 'PV Query: Please clarify if the subject was symptomatic and when they developed symptoms of Covid-19. If the subject was asymptomatic, please confirm in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 16:58:38

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:40:19
User closed query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 13:40:15
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Done' (Site from Safety).	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:26:32
Query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' answered with 'IP withdrawn per source' (Site from Safety).	Nancy Torrence (b) (4) (b) (4)	15 Sep 2020 14:22:46
User opened query 'PV Query: Please report medically relevant clinical course following administration of blinded study vaccine and COVID + test result.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 17:51:52
User opened query 'PV Query: Please clarify if the subject was symptomatic and when they developed symptoms of Covid-19. If the subject was asymptomatic, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Aug 2020 11:42:02
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Aug 2020 11:40:17

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:31:46
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:31:44
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:30:01
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:27:15
Query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19 and provide all relevant details. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:26:35

US3252075
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:11:52
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query Urgent: Information was provided stating the subject began experiencing symptoms of COVID-19 after receiving the vaccination and a positive COVID-19 was documented. If the subject began experiencing symptoms after receiving the vaccine, please create an adverse event of COVID-19 and provide all relevant details. If the subject was experiencing symptoms prior to vaccination or did not experience any symptoms, please clarify in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Aug 2020 14:24:13
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '0'	System	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13
User entered '1'	System	24 Aug 2020 19:08:40

US3252075

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:11:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Joanna Gurrola Mahoney (b) (4)	03 Nov 2020 19:27:18
DataPoint inactivated with code reason code Data not required.	Nancy Torrence (b) (4) (b) (4)	14 Oct 2020 05:15:13

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:43
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 20:52:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	24 Aug 2020 19:10:39
User entered 'No (N)'	Shannon Moyer (b) (4)	08 Aug 2020 17:44:15

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:34:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 21:34:42
Data point term sent to Coder	System	24 Aug 2020 19:22:26
User entered 'Baby Aspirin'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:22
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Indication

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:25
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:27
User entered '81'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:29
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:11:52
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:31
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:34
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:37
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▆ (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6) ▆	23 Oct 2020 16:51:41
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) ▆ (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:45
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:22:23
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 19:22:38
User entered '13 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 19:22:23
User entered '13 Aug ' (non-conformant).	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:51:50
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per source, end date is 19AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:11:43
DataPoint Verified.		05 Nov 2020 18:11:37
Query 'Per source, end date is 19AUG2020. ' answered with 'updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:46:32
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:46:19
User opened query 'Per source, end date is 19AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:53:07
DataPoint Un-verified.		23 Oct 2020 16:52:51
DataPoint Verified.		23 Oct 2020 16:52:47
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:11:45
User entered '19 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:46:19
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'The question "was this medication taken for a solicited event?" is not answered in source and thus cannot be verified. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:11:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:11:07
Query 'The question "was this medication taken for a solicited event?" is not answered in source and thus cannot be verified. ' answered with 'updating ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:46:47
User opened query 'The question "was this medication taken for a solicited event?" is not answered in source and thus cannot be verified. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:53:33
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:11:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:22:23

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 10:22:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 10:22:39
Data point term sent to Coder	System	24 Aug 2020 19:24:31
User entered 'ZPack'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:52
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:55
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:57
User entered '250'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:53:59
User entered 'mg (mg)'	Shannon Moyer (b) (4)	24 Aug 2020 19:23:41
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:02
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:06
User entered 'twice daily (BID)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:07
User entered empty.	Shannon Moyer (b) (4)	24 Aug 2020 19:23:41
	(b) (4)	

FDA-CBER-2022-1614-0713320

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:11:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:10
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:11
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:13
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:15
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:17
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:26:12
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:22
User entered '13 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:26:12
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query '"Was this medication taken for a solicited event?" is not answered in source. Please review. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:10:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:10:31
Query '"Was this medication taken for a solicited event?" is not answered in source. Please review. ' answered with 'updated source' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:48:48
User opened query '"Was this medication taken for a solicited event?" is not answered in source. Please review. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:54:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:26
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:54:24
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:23:41

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:11:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User entered '2'	System	24 Aug 2020 19:23:41

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User entered '1'	System	24 Aug 2020 19:23:41

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:25:16
User entered '804 (804)'	System	24 Aug 2020 19:23:41

FDA-CBER-2022-1614-0713330

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Jan 2021 13:01:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Jan 2021 13:01:26
User closed query 'Per DM CLR: Please review Drug Name Claritan and ensure the correct name has been used as this cannot be referenced. Update name if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:58:44
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: CLARITHROMYCIN, PRODUCTSYNONYM: CLARITIN [CLARITHROMYCIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 23:25:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 23:25:42
Data point term sent to Coder	System	17 Sep 2020 18:55:53
Query 'Per DM CLR: Please review Drug Name Claritan and ensure the correct name has been used as this cannot be referenced. Update name if applicable or provide clarification' answered with 'Corrected spelling' (Site from DM).	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 18:55:34
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 18:55:12
User entered 'CLARITiN' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	17 Sep 2020 18:55:12

PRODUCTION RELEASE (v12.003 EAB) (1725)

2223 of 2459

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review Drug Name Claritan and ensure the correct name has been used as this cannot be referenced. Update name if applicable or provide clarification' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:01:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: CLARITHROMYCIN, PRODUCTSYNONYM: CLARITIN [CLARITHROMYCIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 08:09:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 08:09:43
Data point term sent to Coder	System	24 Aug 2020 19:24:36
User entered 'Claritan'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:51
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:53
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:58:50
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:58
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'has been updated' (Site from DM).	Xavier Morales (b) (4) (b) (4)	22 Sep 2020 14:05:54
User entered '10' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	22 Sep 2020 14:05:46
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:01:58
User entered '1'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:12
User entered 'mg (mg)' reason for change: Data Entry Error	Xavier Morales (b) (4) (b) (4)	22 Sep 2020 14:05:46
User entered 'tablet (TABLET)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:11:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:14
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:17
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:24
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:26
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:29
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:33
User entered '13 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:57:36
User entered '0'	Shannon Moyer (b) (4)	24 Aug 2020 19:24:34
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per source, the stop date is 19AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:47:09
DataPoint Verified.		05 Nov 2020 18:47:07
Query 'Per source, the stop date is 19AUG2020. ' answered with 'updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:49:08
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:49:03
User opened query 'Per source, the stop date is 19AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 17:00:44
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:47:10
User entered '19 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:49:03
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 17:00:48
DataPoint Verified.		23 Oct 2020 17:00:46
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:47:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:47:12
Query 'The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:49:12
User opened query 'The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 17:01:18
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User entered '1'	System	24 Aug 2020 19:24:34

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User entered '1'	System	24 Aug 2020 19:24:34

FDA-CBER-2022-1614-0713348

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:11:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:46
User entered '804 (804)'	System	24 Aug 2020 19:24:34

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 02:47:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 02:47:45
Data point term sent to Coder	System	14 Sep 2020 02:46:50
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:46:30
User entered 'Tylenol' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	14 Sep 2020 02:46:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:31:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:31:47
Data point term sent to Coder	System	24 Aug 2020 19:26:38
User entered 'Tylonel'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:29
User entered 'No (N)'	Shannon Moyer (b) (4)	24 Aug 2020 19:25:53
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:32
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:11:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:34
User entered '325'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:01:35
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:32
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:19:10
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 09:33:15
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 09:33:15
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:35
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:41
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:44
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:46
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:48
User entered '13 Aug 2020'	Shannon Moyer (b) (4)	24 Aug 2020 19:25:53
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 17:02:50
User entered '0'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:48:12
User closed query 'Per source, the stop date is 15AUG2020. ' (Site from CRA).		05 Nov 2020 18:48:10
Query 'Per source, the stop date is 15AUG2020. ' answered with 'updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:49:30
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:49:25
User opened query 'Per source, the stop date is 15AUG2020. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 17:03:14
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

FDA-CBER-2022-1614-0713362

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:48:14
User entered '15 Aug 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:49:25
User entered empty.	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:48:18
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:48:16
Query 'The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' answered with 'updated' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:49:34
User opened query 'The question "was this medication taken for a solicited event?" is not answered. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 17:03:34
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User entered '4'	System	23 Feb 2021 09:33:15
User entered '1'	System	24 Aug 2020 19:25:53

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User entered '1'	System	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:11:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:22:50
User entered '804 (804)'	System	24 Aug 2020 19:25:53

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:25
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)	08 Sep 2020 22:29:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:29:56
Data point term sent to Coder	System	08 Sep 2020 22:28:36
User entered 'ZPack'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:27
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 17:12:08
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'the drug is given for COVID indication, it is correct per source' (Site from DM).	Shannon Moyer (b) (4) (b) (4)	08 Feb 2021 04:50:24
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:35:35
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:28
User entered 'COVID Positive'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:30
User entered '250'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:33
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:36
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:19:18
User closed query 'Per source, ConMed frequency is listed as once daily. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:19:15
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Per source, ConMed frequency is listed as once daily. Please verify and update EDC accordingly.' answered with 'Corrected' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 09:34:01
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 09:33:43
User opened query 'Per source, ConMed frequency is listed as once daily. Please verify and update EDC accordingly.' (Site from CRA).		22 Feb 2021 19:23:04
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:55:05
User entered 'four times daily (QID)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	24 Nov 2020 16:55:05
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:38
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:40
User entered empty.	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:42
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:47
User entered empty.	Shannon Moyer (b) (4)	08 Sep 2020 22:27:42
	(b) (4)	

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:49
User entered '14 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:50
User entered '0'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:54
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:55:56
User entered '19 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User closed query '"Was this medication taken for a solicited event?" is not answered in source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:48:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:48:38
Query '"Was this medication taken for a solicited event?" is not answered in source. Please review and reconcile. ' answered with 'updated source ' (Site from CRA).	Joanna Gurrola Mahoney (b) (4)	29 Oct 2020 04:50:28
User opened query '"Was this medication taken for a solicited event?" is not answered in source. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 16:56:32
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 16:56:08
DataPoint Verified.		23 Oct 2020 16:55:58
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User entered '1'	System	23 Feb 2021 09:33:43
User entered '4'	System	24 Nov 2020 16:55:05
User entered '1'	System	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User entered '1'	System	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:11:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:24:18
User entered '804 (804)'	System	08 Sep 2020 22:27:42

US3252075

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:11:52

Were any concomitant procedures performed?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:33:02
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Aug 2020 20:48:11
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	08 Aug 2020 17:44:42

US3252075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:11:52

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:23:12
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 19:41:16
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 16:34:20
User closed query 'Per source, subject received COVID+ results on 19-Aug-2020. Therefore, per eCRF Guidelines, date of dosing discontinuation should be 19-Aug-2020. Please verify and update EDC accordingly. ' (Site from CRA).		08 Mar 2021 16:34:17
Query 'Per source, subject received COVID+ results on 19-Aug-2020. Therefore, per eCRF Guidelines, date of dosing discontinuation should be 19-Aug-2020. Please verify and update EDC accordingly. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 08:17:12
Signature has been broken.	(b) (4), (b) (6)	08 Mar 2021 08:14:15
User entered '19 Aug 2020' reason for change: Data Entry Error		08 Mar 2021 08:14:15
User opened query 'Per source, subject received COVID+ results on 19-Aug-2020. Therefore, per eCRF Guidelines, date of dosing discontinuation should be 19-Aug-2020. Please verify and update EDC accordingly. ' (Site from CRA).		05 Mar 2021 22:15:53
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
User entered '13 Aug 2020'	(b) (4), (b) (6)	06 Nov 2020 20:51:00

US3252075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:11:52

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:23:12
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:51:36
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	06 Nov 2020 20:51:00

US3252075

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:11:52

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 10:23:12
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 18:51:38
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:51:00

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

FDA-CBER-2022-1614-0713402

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

FDA-CBER-2022-1614-0713403

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓ (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).		05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:11:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
User entered '25/Aug/2020 10:48'	System	25 Aug 2020 14:48:23

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:11:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 14:48:23

FDA-CBER-2022-1614-0713423

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▨ (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

FDA-CBER-2022-1614-0713434

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).		05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
User entered '16/Sep/2020 09:40'	System	16 Sep 2020 13:40:55

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:11:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:59:43
User entered '1'	(b) (4), (b) (6)	16 Sep 2020 13:40:55

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:11:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▓ (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6) ▓	05 Nov 2020 17:36:15
User entered '04/Nov/2020 15:59'	System	04 Nov 2020 15:59:59

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)	05 Mar 2021 20:10:32
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:46:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
User entered '1'	(b) (4), (b) (6)	04 Nov 2020 15:59:59

FDA-CBER-2022-1614-0713459

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

FDA-CBER-2022-1614-0713461

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:11:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:26
User entered '16/Nov/2020 17:46'	System	16 Nov 2020 17:46:49

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:11:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:28
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 18:24:30
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 17:46:49

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▨ (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:11:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:35
User entered '16/Nov/2020 18:24'	System	16 Nov 2020 18:24:46

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:11:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Nov 2020 13:56:47
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 18:24:46

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ██ (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

FDA-CBER-2022-1614-0713507

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

FDA-CBER-2022-1614-0713511

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:11:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:44
User entered '22/Nov/2020 08:57'	System	22 Nov 2020 13:57:02

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:11:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
User entered '1'	(b) (4), (b) (6)	22 Nov 2020 13:57:02

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 11 Aug 2021 22:11:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:49
User entered '24/Nov/2020 10:37'	System	24 Nov 2020 15:37:29

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 11 Aug 2021 22:11:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:20:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 19:48:04
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 15:37:29

SAEID

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

FDA-CBER-2022-1614-0713544

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 11 Aug 2021 22:11:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis ▨ (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6) ▨	04 Feb 2021 20:21:07
User entered '01/Dec/2020 19:48'	System	01 Dec 2020 19:48:18

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 11 Aug 2021 22:11:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:08
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 12:28:23
User entered '1'	(b) (4), (b) (6)	01 Dec 2020 19:48:18

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'USA-US108-2020-MRNA-1273-P301000001'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'No (N)'	System	25 Aug 2020 14:46:52

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Joel'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Mary Jane Faith'	System	25 Aug 2020 14:46:52

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Solis'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Bagunas'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered '5201 N. 10th Street'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '3636 Robin St. Anak Pawis,'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'Mcallen'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered 'Cainta'	System	25 Aug 2020 14:46:52

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'TX'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '40'	System	25 Aug 2020 14:46:52

FDA-CBER-2022-1614-0713562

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 22:18:16
User closed query 'Please update to correct site postal code.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 22:18:13
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
Query 'Please update to correct site postal code.' answered with 'updated postal code' (Site from CRA)	(b) (4), (b) (6)	24 Feb 2021 03:33:11
Un-reviewed for Safety.		24 Feb 2021 03:32:49
User entered '78504' reason for change: Data Entry Error		24 Feb 2021 03:32:49
User opened query 'Please update to correct site postal code.' (Site from CRA).		22 Feb 2021 19:19:52
DataPoint Un-verified.		22 Feb 2021 19:19:41
DataPoint Verified.		22 Feb 2021 19:19:39
Reviewed for Safety.		01 Dec 2020 19:48:04
Un-reviewed for Safety.	System	24 Nov 2020 15:37:29
User entered 'carmpa'	System	24 Nov 2020 15:37:29
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 15:36:51
Un-reviewed for Safety.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Un-verified.	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
User entered '78504' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	23 Nov 2020 22:27:22
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:46:24
Amendment Manager: User entered 'carmpa'	System	14 Sep 2020 21:46:24
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 14:48:03
User entered '1900'	System	25 Aug 2020 14:46:52

US3252075
Folder: SAE USA-US108-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:11:52

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:36:15
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Sep 2020 13:40:42
User entered 'US' (non-conformant).	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:11:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '9'	System	11 Dec 2020 12:28:34
User entered '8'	System	01 Dec 2020 19:48:18
User entered '7'	System	24 Nov 2020 15:37:29
User entered '6'	System	22 Nov 2020 13:57:02
User entered '5'	System	16 Nov 2020 18:24:46
User entered '4'	System	16 Nov 2020 17:46:49
User entered '3'	System	04 Nov 2020 15:59:59
User entered '2'	System	16 Sep 2020 13:40:55
User entered '1'	System	25 Aug 2020 14:48:23

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 11 Aug 2021 22:11:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:13
User entered '11/Dec/2020 07:28'	System	11 Dec 2020 12:28:34

US3252075

Folder: SAE USA-US108-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 11 Aug 2021 22:11:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 20:10:32
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:21:14
User entered '1'	(b) (4), (b) (6)	11 Dec 2020 12:28:34