US3402196 (Prod: Meridian Clinical Research, LLC)

Form: Participant Creation
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

Participant ID   US3402196

mRNA-1273-P301 Completion Guidelines

US3402196

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	SCRN

US3402196

Folder: Screening

Form: Demographics

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
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) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Date of Informed Consent *(dd MMM yyyy)*	3 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) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Did the participant meet all eligibility criteria?　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Were any significant conditions reported?   Yes ●

                                                                                                        No ○

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4)   **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	3 AUG 2020
Time of assessment *(00:00-23:59)*	07:43 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 07:43
Height *(xxx.x)*	166.5 cm
Weight *(xxx.x)*	94.8 kg
BMI *(xxx.x)*	34.19636 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   3 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: [(b) (4)] **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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	MECHANIC

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: [(b) (4)] **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	3 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: ▨ (b) (4) ▨ **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

What was the date of randomization? *(dd MMM yyyy)*	03 AUG 2020
What was the participant's randomization number?	184441

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 ●

US3402196
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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)*	3 AUG 2020
Time of assessment *(00:00-23:59)*	07:43 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 07:43
Temperature *(xxx.x)*	36.5 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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)*	3 AUG 2020
Time of assessment *(00:00-23:59)*	09:43 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 09:43
Temperature *(xxx.x)*	96.4 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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)*	3 AUG 2020
What was the treatment time? *(00:00-23:59)*	08:32 (24 HR)
Treatment Date and Time (derived)	3 AUG 2020 08:32
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	3 AUG 2020
Collection time *(00:00-23:59)*	08:06 (24 HR)
Collection date and time (derived)	3 AUG 2020 08:06

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4)   **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*			3 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:00	3 AUG 2020 08:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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**	96.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○ / No ●

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

PC Time Stamp	03 AUG 2020 09:05
PC Open Date & Time	03 AUG 2020 08:52
PC Close Date & Time	03 AUG 2020 11:22

FDA-CBER-2022-1614-1735959

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**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	03 AUG 2020 18:53
PC Open Date & Time	03 AUG 2020 12:17
PC Close Date & Time	04 AUG 2020 11:59

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 2

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	96.1 °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	04 AUG 2020 18:09
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

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**	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	05 AUG 2020 18:02
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31

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**	96.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 AUG 2020 17:59
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	96.8 °F

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

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

PC Time Stamp	07 AUG 2020 18:04
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

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**	97.0 °F

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

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

PC Time Stamp	08 AUG 2020 18:06
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 AUG 2020 16:43
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

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	03 AUG 2020 09:06
PC Open Date & Time	03 AUG 2020 08:52
PC Close Date & Time	03 AUG 2020 11:22

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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	03 AUG 2020 18:54
PC Open Date & Time	03 AUG 2020 12:17
PC Close Date & Time	04 AUG 2020 11:59

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31

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	04 AUG 2020 18:10
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31

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	05 AUG 2020 18:03
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

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	06 AUG 2020 18:00
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 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	07 AUG 2020 18:04
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 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	08 AUG 2020 18:07
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

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	09 AUG 2020 16:44
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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 ◯

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	03 AUG 2020 09:07
PC Open Date & Time	03 AUG 2020 08:52
PC Close Date & Time	03 AUG 2020 11:22

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31

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 ○

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

PC Time stamp	03 AUG 2020 18:54
PC Open Date & Time	03 AUG 2020 12:17
PC Close Date & Time	04 AUG 2020 11:59

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

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	04 AUG 2020 18:11
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

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	05 AUG 2020 18:04
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

TIMEPOINT	DAY 4

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

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

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

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

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

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

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

	Yes ◯
PC Time stamp	06 AUG 2020 18:01
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31

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-2022-1614-1735985

	Yes ◯
PC Time stamp	07 AUG 2020 18:05
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31

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	08 AUG 2020 18:08
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31

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	09 AUG 2020 16:45
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402196
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 AUG 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3402196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 17 AUG 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3402196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 AUG 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3402196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

US3402196
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	31 AUG 2020
Time of assessment *(00:00-23:59)*	07:26 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 07:26
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	190 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	31 AUG 2020
Time of assessment *(00:00-23:59)*	08:39 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:39
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	190 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?   Yes ⬤

No ◯

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

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

US3402196
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: [(b) (4)] **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

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)*	31 AUG 2020
What was the treatment time? *(00:00-23:59)*	08:08 (24 HR)
Treatment Date and Time (derived)	31 AUG 2020 08:08
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	31 AUG 2020
Collection time *(00:00-23:59)*	07:55 (24 HR)
Collection date and time (derived)	31 AUG 2020 07:55

US3402196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*			31 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:48	31 AUG 2020 07:48
Nasopharyngeal Swab 2	No		

Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4)   **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○ No ●

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

PC Time Stamp	31 AUG 2020 08:57
PC Open Date & Time	31 AUG 2020 08:28
PC Close Date & Time	31 AUG 2020 10:58

FDA-CBER-2022-1614-1736005

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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**	97.9 °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	31 AUG 2020 19:03
PC Open Date & Time	31 AUG 2020 11:53
PC Close Date & Time	01 SEP 2020 11:59

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 2

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

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

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

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

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

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

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

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

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

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

PC Time Stamp	01 SEP 2020 16:55
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	02 SEP 2020 19:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	03 SEP 2020 20:18
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

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**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	04 SEP 2020 17:58
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

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	05 SEP 2020 17:52
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31

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**	97.5 °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	06 SEP 2020 16:51
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 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	31 AUG 2020 08:57
PC Open Date & Time	31 AUG 2020 08:28
PC Close Date & Time	31 AUG 2020 10:58

FDA-CBER-2022-1614-1736013

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	31 AUG 2020 19:04
PC Open Date & Time	31 AUG 2020 11:53
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-1736014

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	01 SEP 2020 16:56
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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	02 SEP 2020 19:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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	03 SEP 2020 20:18
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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	04 SEP 2020 17:58
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 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	05 SEP 2020 17:53
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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	06 SEP 2020 16:52
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

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 ◯

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	31 AUG 2020 08:58
PC Open Date & Time	31 AUG 2020 08:28
PC Close Date & Time	31 AUG 2020 10:58

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

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯
PC Time stamp	31 AUG 2020 19:05
PC Open Date & Time	31 AUG 2020 11:53
PC Close Date & Time	01 SEP 2020 11:59

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31

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	01 SEP 2020 16:56
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31

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 ⬤

FDA-CBER-2022-1614-1736027

	Yes ◯
PC Time stamp	02 SEP 2020 19:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31

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 ●

	Yes ◯
PC Time stamp	03 SEP 2020 20:19
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31

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-2022-1614-1736031

	Yes ◯
PC Time stamp	04 SEP 2020 17:59
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31

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	05 SEP 2020 17:53
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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 ●

FDA-CBER-2022-1614-1736035

	Yes ◯
PC Time stamp	06 SEP 2020 16:52
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 8 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ●

                                                                          No ◯

Continuing Flag   1

US3402196

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ⬤

                                                                   No ◯

Continuing Flag   1

US3402196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

| 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

US3402196
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3402196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT3

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **15 Feb 2021 16:58:37**

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	29 SEP 2020
Time of assessment *(00:00-23:59)*	07:35 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 07:35
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ●
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Was the physical examination performed?   Yes ◯

No ⬤

Date of examination *(dd MMM yyyy)* _____

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

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	29 SEP 2020
Collection time *(00:00-23:59)*	07:40 (24 HR)
Collection date and time (derived)	29 SEP 2020 07:40

US3402196
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 16:58:37**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 OCT 2020 11:02:53
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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	11 OCT 2020 10:57:21
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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	18 OCT 2020 18:30:40
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 10:03:20
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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	08 NOV 2020 18:48:36
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 07:29:45
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 02:44:31
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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	28 NOV 2020 13:20:30
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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	06 DEC 2020 08:47:49
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 131

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

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

Fever (Temperature $\geq$ 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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ⬤
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 09:31:47
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚫
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚫
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Date and time of submission	25 DEC 2020 22:47:30
Patient Cloud Open Date & Time	23 DEC 2020 00:01

Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT   DAY 152

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○
	Yes ●
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ●
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 06:39:15
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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-2022-1614-1736067

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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	28 JAN 2021 09:39:08
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 07:31:00
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 15:25:52
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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-2022-1614-1736072

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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	27 FEB 2021 21:16:42
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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-2022-1614-1736075

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 222**

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

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

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

FDA-CBER-2022-1614-1736077

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT DAY 229

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 236

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

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

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

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

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

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

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

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

FDA-CBER-2022-1614-1736081

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 15:09:47
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 APR 2021 14:59:20
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 15:48:51
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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	22 APR 2021 18:13:43
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 11:23:09
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 278**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 285

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

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

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

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

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ⃝

FDA-CBER-2022-1614-1736092

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 306**

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 313**

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ◯

FDA-CBER-2022-1614-1736102

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 334**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have 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-2022-1614-1736104

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 341**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

FDA-CBER-2022-1614-1736106

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 348**

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

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

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

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

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 355

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 369**

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have 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-2022-1614-1736116

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ◯

FDA-CBER-2022-1614-1736118

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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-2022-1614-1736120

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ⬭

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ⬭

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 411

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ⭕

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 425**

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

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

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

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

FDA-CBER-2022-1614-1736130

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 432**

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

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

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

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

FDA-CBER-2022-1614-1736132

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 439

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT   DAY 446

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 453**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT   DAY 460

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 467

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

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

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

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

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

TIMEPOINT   DAY 474

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

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

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

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

FDA-CBER-2022-1614-1736144

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 481

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have 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-2022-1614-1736146

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have 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-2022-1614-1736150

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT   DAY 502

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

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ⭕

FDA-CBER-2022-1614-1736154

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 530**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

FDA-CBER-2022-1614-1736160

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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):

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ⚪

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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):

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-2022-1614-1736166

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 558

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

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

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

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

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 565**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 572**

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 579**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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):

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-2022-1614-1736176

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have 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-2022-1614-1736178

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ⭕

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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-2022-1614-1736188

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT DAY 635

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have 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-2022-1614-1736192

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 649

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

No ◯
Yes ◯

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

No ◯
Yes ◯

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

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

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

No ◯
Yes ◯

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

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

No ◯
Yes ◯

FDA-CBER-2022-1614-1736194

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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):

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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-2022-1614-1736198

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 670**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have 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 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have 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	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 698

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ⭕

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

FDA-CBER-2022-1614-1736211

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 719

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 733

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

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

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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):

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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):

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 ⬭

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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):

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 ⃝

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	**DAY 789**

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

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

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 ◯

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ◯

FDA-CBER-2022-1614-1736236

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

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		22 APR 2021 18:14:03

US3402196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **08 Mar 2021 22:19:44**

Generated On: 11 Aug 2021 22:33:31

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 OCT 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **08 Mar 2021 22:19:44**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ●

                                                                                                                   No ○

Continuing Flag   1

US3402196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?   Yes ⬤

                                                                          No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*   27 NOV 2020

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

                                                            Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 22:46:32**
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 DEC 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?　　　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3402196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4)   **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?   Yes ●

                                                                    No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   25 JAN 2021

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

                                                     Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3402196

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT4

US3402196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	23 FEB 2021
Time of assessment *(00:00-23:59)*	09:06 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:06
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402196

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

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: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	23 FEB 2021
Collection time *(00:00-23:59)*	09:20 (24 HR)
Collection date and time (derived)	23 FEB 2021 09:20

US3402196

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ●

      No ◯

Continuing Flag   1

US3402196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 MAR 2021
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                                        No ◯

Continuing Flag   1

US3402196
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31

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 _____

Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID-19 Contact
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

Date of Contact	29 DEC 2020
Time of Contact	07:30
Date and Time of Contact (derived)	29 DEC 2020 07:30
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 ◯

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	17 DEC 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 ◯

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Not Done ○

Fatigue   None ●

                                                     Mild ○

                                                 Moderate ○

                                                   Severe ○

                                                 Not Done ○

Muscle Aches (Myalgia)   None ●

                                                     Mild ○

                                                 Moderate ○

                                                   Severe ○

                                                 Not Done ○

Body Aches   None ●

                                                     Mild ○

                                                 Moderate ○

                                                   Severe ○

                                                 Not Done ○

Headache   None ●

                                                     Mild ○

                                                 Moderate ○

                                                   Severe ○

                                                 Not Done ○

New Loss of Taste   None ●

                                                     Mild ○

                                                 Moderate ○

                                                   Severe ○

                                                 Not Done ○

New Loss of Smell   None ●

                                                     Mild ○

                                                 Moderate ○

                                                   Severe ○

                                                 Not Done ○

Nasal Congestion

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

Runny Nose (Rhinorrhea)

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

Nausea

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

Vomiting

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

Diarrhea

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

Sore Throat

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

Symptom Day

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

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	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	18 DEC 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-2022-1614-1736262

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 ○

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) 26 Apr 2021 22:46:30
Generated On: 11 Aug 2021 22:33:31

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-2022-1614-1736265

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	19 DEC 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 ○

FDA-CBER-2022-1614-1736268

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 DEC 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 ○

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) 26 Apr 2021 22:46:30
Generated On: 11 Aug 2021 22:33:31

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 DEC 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 ○

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	22 DEC 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 ○

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 DEC 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 ◯

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Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

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

Runny Nose (Rhinorrhea)

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

Nausea

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

Vomiting

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

Diarrhea

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

Sore Throat

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

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

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 DEC 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 ○

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 DEC 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 ○

Symptom Day

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

	Day 33 ○
	Day 34 ○
	Day 35 ○
	Day 36 ○
	Day 37 ○
	Day 38 ○
	Day 39 ○
	Day 40 ○
Date	26 DEC 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 ○

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

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

Runny Nose (Rhinorrhea)

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

Nausea

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

Vomiting

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

Diarrhea

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

Sore Throat

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

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (11)
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

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

	Day 33 ⭘
	Day 34 ⭘
	Day 35 ⭘
	Day 36 ⭘
	Day 37 ⭘
	Day 38 ⭘
	Day 39 ⭘
	Day 40 ⭘
Date	27 DEC 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 ⭘

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

	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 ○

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US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

Runny Nose (Rhinorrhea)	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

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

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

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

Sore Throat	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	28 DEC 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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 ○

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Data signed: (b) (4) 26 Apr 2021 22:46:30
Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

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

Date	29 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	36.3 C

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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (14)
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

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

	Day 33 ○
	Day 34 ○
	Day 35 ○
	Day 36 ○
	Day 37 ○
	Day 38 ○
	Day 39 ○
	Day 40 ○
Date	30 DEC 2020
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	99.6 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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 ◯

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	31 DEC 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	99.2 F
Chills	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ○

Mild ●

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia)

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache

None ○

Mild ●

Moderate ○

Severe ○

Not Done ○

New Loss of Taste

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

None ◯
Mild ⬤
Moderate ◯
Severe ◯
Not Done ◯

Runny Nose (Rhinorrhea)

None ◯
Mild ⬤
Moderate ◯
Severe ◯
Not Done ◯

Nausea

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Vomiting

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

Diarrhea

None ◯
Mild ⬤
Moderate ◯
Severe ◯
Not Done ◯

Sore Throat

None ⬤
Mild ◯
Moderate ◯
Severe ◯
Not Done ◯

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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	01 JAN 2021
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	98.8 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 ◯

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	2 JAN 2021
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	98.4 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ◯

Mild ⬤

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ◯

Mild ⬤

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

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

Runny Nose (Rhinorrhea)

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

Nausea

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

Vomiting

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

Diarrhea

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

Sore Throat

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

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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	03 JAN 2021
Assessment Not Done	False
O2 Saturation	94 %
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 ○

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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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	04 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.2 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

FDA-CBER-2022-1614-1736330

	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-2022-1614-1736332

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (20)
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

	Day 33 ○
	Day 34 ○
	Day 35 ○
	Day 36 ○
	Day 37 ○
	Day 38 ○
	Day 39 ○
	Day 40 ○
Date	05 JAN 2021
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	98.0 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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

	Day 33 ○
	Day 34 ○
	Day 35 ○
	Day 36 ○
	Day 37 ○
	Day 38 ○
	Day 39 ○
	Day 40 ○
Date	06 JAN 2021
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 ○

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 ○

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (22)
Data signed: (b) (4)   **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

FDA-CBER-2022-1614-1736341

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

Date	07 JAN 2021
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.4 F
Chills	None ⬤
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
Cough	None ○
	Mild ⬤
	Moderate ○
	Severe ○
	Not Done ○
Shortness of Breath	None ○
	Mild ⬤
	Moderate ○
	Severe ○
	Not Done ○
Difficulty Breathing	None ⬤
	Mild ○
	Moderate ○
	Severe ○

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

FDA-CBER-2022-1614-1736344

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

	Day 33 ⬭
	Day 34 ⬭
	Day 35 ⬭
	Day 36 ⬭
	Day 37 ⬭
	Day 38 ⬭
	Day 39 ⬭
	Day 40 ⬭
Date	08 JAN 2021
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.5 F
Chills	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬭
	Mild ⬤
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬭
	Mild ⬤
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	09 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
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 ◯

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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	10 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.4 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

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

Runny Nose (Rhinorrhea)

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

Nausea

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

Vomiting

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

Diarrhea

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

Sore Throat

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

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Data signed: (b) (4)   **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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	◯

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

	Day 33 ◯
	Day 34 ◯
	Day 35 ◯
	Day 36 ◯
	Day 37 ◯
	Day 38 ◯
	Day 39 ◯
	Day 40 ◯
Date	11 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.5 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

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	12 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.1 F

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

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

Shortness of Breath	
	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○

Difficulty Breathing	
	None ●
	Mild ○
	Moderate ○
	Severe ○

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Not Done ⚪

Fatigue

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Muscle Aches (Myalgia)

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Body Aches

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Headache

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

New Loss of Taste

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

New Loss of Smell

None ⚫

Mild ⚪

Moderate ⚪

Severe ⚪

Not Done ⚪

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Symptom Day

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

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

Date	13 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.3 F
Chills	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ⬤
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (33)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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	14 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
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 ◯

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	15 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.3 F
Chills	None ●
	Mild ◯
	Moderate ◯
	Severe ◯
	Not Done ◯
Cough	None ◯
	Mild ●
	Moderate ◯
	Severe ◯
	Not Done ◯
Shortness of Breath	None ◯
	Mild ●
	Moderate ◯
	Severe ◯
	Not Done ◯
Difficulty Breathing	None ●
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ◯

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

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

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

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

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

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

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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	16 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	96.8 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	◯

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (37)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

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

Date	17 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.4 F

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

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

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

Difficulty Breathing	None ⬤
	Mild ◯
	Moderate ◯
	Severe ◯

Not Done ○

Fatigue

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Muscle Aches (Myalgia)

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Body Aches

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Headache

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Taste

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

New Loss of Smell

None ●

Mild ○

Moderate ○

Severe ○

Not Done ○

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Data signed: ▨ (b) (4) ▨ **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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

	Day 33 ●
	Day 34 ○
	Day 35 ○
	Day 36 ○
	Day 37 ○
	Day 38 ○
	Day 39 ○
	Day 40 ○
Date	18 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.2 F
Chills	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
Cough	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○
Shortness of Breath	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○
Difficulty Breathing	None ●
	Mild ○
	Moderate ○
	Severe ○

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (39)
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

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 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	97.3 F
Chills	None ●
	Mild ⊙
	Moderate ⊙
	Severe ⊙
	Not Done ⊙
Cough	None ⊙
	Mild ●
	Moderate ⊙
	Severe ⊙
	Not Done ⊙
Shortness of Breath	None ⊙
	Mild ●
	Moderate ⊙
	Severe ⊙
	Not Done ⊙
Difficulty Breathing	None ●
	Mild ⊙
	Moderate ⊙
	Severe ⊙

Not Done ◯

Fatigue

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia)

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell

None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (39)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (40)

Data signed: (b) (4)   **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.4 F
Chills	None ●
	Mild ○
	Moderate ○
	Severe ○
	Not Done ○
Cough	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○
Shortness of Breath	None ○
	Mild ●
	Moderate ○
	Severe ○
	Not Done ○
Difficulty Breathing	None ●
	Mild ○
	Moderate ○
	Severe ○

Not Done ◯

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

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

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

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

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

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

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (41)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.3 F
Chills	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Cough	None ⭕
	Mild ⬤
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Shortness of Breath	None ⭕
	Mild ⬤
	Moderate ⭕
	Severe ⭕
	Not Done ⭕
Difficulty Breathing	None ⬤
	Mild ⭕
	Moderate ⭕
	Severe ⭕

Not Done ◯

Fatigue None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Muscle Aches (Myalgia) None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Body Aches None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

Headache None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Taste None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

New Loss of Smell None ⬤

Mild ◯

Moderate ◯

Severe ◯

Not Done ◯

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (41)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 ○

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (42)
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

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	22 JAN 2021
Assessment Not Done	False
O2 Saturation	96 %
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 ⚪

Not Done ◯

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

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

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

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

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

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

Nasal Congestion

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

Runny Nose (Rhinorrhea)

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

Nausea

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

Vomiting

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

Diarrhea

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

Sore Throat

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

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (43)
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

	Day 33 ⚪
	Day 34 ⚪
	Day 35 ⚪
	Day 36 ⚪
	Day 37 ⚪
	Day 38 ⚫
	Day 39 ⚪
	Day 40 ⚪

Date	23 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
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 ◯

Nasal Congestion

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

Runny Nose (Rhinorrhea)

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

Nausea

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

Vomiting

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

Diarrhea

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

Sore Throat

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

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 JAN 2021
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.2 F
Chills	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Cough	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Shortness of Breath	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭
	Not Done ⬭
Difficulty Breathing	None ⬤
	Mild ⬭
	Moderate ⬭
	Severe ⬭

Not Done ○

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

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

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

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

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

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

Nasal Congestion

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Runny Nose (Rhinorrhea)

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Nausea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Vomiting

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Diarrhea

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Sore Throat

None ●
Mild ○
Moderate ○
Severe ○
Not Done ○

Date of Visit	29 DEC 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	29 DEC 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   Yes ⬤
at sea level?
                                                                          No ◯

If Yes, provide:

  Start Date   30 DEC 2020

  End Date   2 JAN 2021

  Oxygen Saturation   93 %

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?   Yes ◯

                                                                          No ⬤

If Yes, provide:

  Start Date

  End Date

  PaO2

Did the subject have Respiratory failure?   Yes ◯

                                                                          No ⬤

  Start Date

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?   Yes ◯

                                                                          No ⬤

  Start Date

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

Ventilator Support:

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

Evidence of Shock:

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

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

| 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 _____

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Generate Next COVID-19 Assessment
Yes ●
No ○

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	31 DEC 2020
Day 5	Yes	02 JAN 2021
Day 7	Yes	04 JAN 2021
Day 9	Yes	6 JAN 2021
Day 14	Yes	08 JAN 2021
Day 21	Yes	15 JAN 2021
Day 28	No	25 JAN 2021

US3402196
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 22:46:32**
Generated On: 11 Aug 2021 22:33:31

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

Visit date (dd MMM yyyy)	29 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | SICKD1 |

US3402196

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	29 DEC 2020
Time of assessment *(00:00-23:59)*	07:30 (24 HR)
Vital Signs Date and Time (derived)	29 DEC 2020 07:30
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	99 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)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402196

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?	Yes ●
	No ○

Date of examination *(dd MMM yyyy)*   29 DEC 2020

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

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Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ◯
	NA (COVID-19 Negative) ◯
Date of Collection	29 DEC 2020

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 22:46:30**
Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	25 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SICKD28

US3402196

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: ▨ (b) (4) ▨ **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	25 JAN 2021
Time of assessment *(00:00-23:59)*	14:46 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 14:46
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	206 lb
Temperature *(xxx.x)*	36.5 C
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)*	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed? Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)* 25 JAN 2021

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

US3402196

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) **26 Apr 2021 22:46:30**

Generated On: 11 Aug 2021 22:33:31

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ●
	No ◯
	NA (COVID-19 Negative) ◯
Date of Collection	25 JAN 2021

US3402196

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:46:32

Generated On: 11 Aug 2021 22:33:31

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

Visit date (dd MMM yyyy)	26 JAN 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)*	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	26 JAN 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Will participant receive mRNA-1273?	Yes ●
	No ○
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3402196

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

Form: Vital Signs - Dosing

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

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

US3402196

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

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)*	26 JAN 2021
Time of assessment *(00:00-23:59)*	08:25 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 08:25
Temperature *(xxx.x)*	36.2 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	112 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

US3402196

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

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)*	26 JAN 2021
Time of assessment *(00:00-23:59)*	09:30 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 09:30
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ●
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	88 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	168 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

US3402196

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

Form: Physical Examination

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?	Yes ●
	No ○

Date of examination *(dd MMM yyyy)*   26 JAN 2021

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

Was study treatment given?	Yes ●
	No ◯

If No, reason not given

Participant declined due to Adverse Event	◯
Physician withheld dose due to Adverse Event	◯
Death	◯
Lost To Follow-Up	◯
Physician Decision	◯
Pregnancy	◯
Protocol Deviation	◯
Study Terminated by Sponsor	◯
Withdrawal of Consent by Participant	◯
Confirmed COVID-19	◯
Other	◯

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

What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	26 JAN 2021
What was the treatment time? *(00:00-23:59)*	08:55 (24 HR)
Treatment Date and Time (derived)	26 JAN 2021 08:55
Which arm was used to give treatment?	Left Arm ●
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	26 JAN 2021
Collection time *(00:00-23:59)*	08:15 (24 HR)
Collection date and time (derived)	26 JAN 2021 08:15

US3402196

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	26 JAN 2021
Collection time *(00:00 - 23:59)*	08:18
Collection Date and Time (derived)	26 JAN 2021 08:18

US3402196

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

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3402196
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 22:46:33**
Generated On: 11 Aug 2021 22:33:31

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*   3 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ●

                                                             No ◯

Continuing Flag	1
OLD29 Placebo Flag	1

US3402196
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 22:46:32**
Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	OLD29

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	23 FEB 2021
Time of assessment *(00:00-23:59)*	09:06 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 09:06
Temperature *(xxx.x)*	36.6 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	23 FEB 2021
Time of assessment *(00:00-23:59)*	10:02 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:02
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3402196

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4)   **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   23 FEB 2021

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

| Was study treatment given? | Yes ⬤ |
| | No ◯ |

If No, reason not given	Participant declined due to Adverse Event ◯
	Physician withheld dose due to Adverse Event ◯
	Death ◯
	Lost To Follow-Up ◯
	Physician Decision ◯
	Pregnancy ◯
	Protocol Deviation ◯
	Study Terminated by Sponsor ◯
	Withdrawal of Consent by Participant ◯
	Confirmed COVID-19 ◯
	Other ◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	23 FEB 2021
What was the treatment time? *(00:00-23:59)*	09:30 (24 HR)
Treatment Date and Time (derived)	23 FEB 2021 09:30
Which arm was used to give treatment?	Left Arm ⬤
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3402196
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 22:46:32**
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3402196

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 2 MAR 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3402196

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) **26 Apr 2021 22:46:33**

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3402196

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	OLD57

US3402196
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 22:46:32**
Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes ◯
	No ⬤

Date of assessment *(dd MMM yyyy)* _____

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

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral ◯
	Axillary ◯
	Other ◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

Was the physical examination performed?   Yes ◯

                                                                           No ⬤

Date of examination *(dd MMM yyyy)*   _____

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

US3402196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	26 MAR 2021
Collection time *(00:00-23:59)*	08:59 (24 HR)
Collection date and time (derived)	26 MAR 2021 08:59

US3402196

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **14 Mar 2021 14:38:53**

Generated On: 11 Aug 2021 22:33:31

Did the participant experience any adverse events?   Yes ●

                                                            No ○

If Yes, enter details on the Adverse Events form.

AEID	
Adverse event	ABCESSED RIGHT UPPER FIRST PREMOLAR

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)* 26 DEC 2020
Start time *(00:00-23:59)*
AE start date and time (derived)

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)* 6 JAN 2021
End time *(00:00-23:59)*
AE End Date and Time (derived)

Severity Grade 1/Mild ○ Grade 2/Moderate ● Grade 3/Severe ○ Grade 4 ○

Is the adverse event serious? Yes ○ No ●

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU? Yes ○ No ○ Unknown ○

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related	●
	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	
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)	

AEID	USA-US059-2021-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)*	17 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	25 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity Grade 1/Mild ○ Grade 2/Moderate ● Grade 3/Severe ○ Grade 4 ○

Is the adverse event serious? Yes ○ No ●

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU? Yes ○ No ○ Unknown ○

Number of Days in ICU	
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	
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)	

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **08 Apr 2021 23:30:26**

Generated On: 11 Aug 2021 22:33:31

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

No ◯

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

Name of Medication	VALSARTAN

Prophylaxis	Yes ◯
	No ●

Indication	HYPERTENSION

Dose per administration	320

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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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)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
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 ●

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US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **08 Apr 2021 23:30:25**

Generated On: 11 Aug 2021 22:33:31

Name of Medication	HYDROCHLOROTHIAZIDE

Prophylaxis

Yes ◯
No ⬤

Indication	HYPERTENSION
Dose per administration	25

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)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
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 ●

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:30:25

Generated On: 11 Aug 2021 22:33:31

Name of Medication	AMOXICILLIN

Prophylaxis	Yes ◯
	No ⬤

Indication	ABCESSED TOOTH
Dose per administration	875

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)*	26 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	5 JAN 2021
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	PREDNISONE

Prophylaxis	Yes ◯
	No ⬤

Indication	SARS COVID 19
Dose per administration	40

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **08 Apr 2021 23:30:25**

Generated On: 11 Aug 2021 22:33:31

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)*	30 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	08 JAN 2021
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-2022-1614-1736464

US3402196

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **08 Apr 2021 23:30:26**

Generated On: 11 Aug 2021 22:33:31

Were any concomitant procedures performed?   Yes ⬭

No ⬤

If yes, please complete Concomitant Procedures form.

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ◯

SAE (specify) ◯

Death ◯

Lost To Follow-up ◯

Physician decision (specify) ◯

Pregnancy ◯

Protocol deviation (specify) ◯

Study Terminated By Sponsor ◯

Withdrawal of consent by
participant (specify) ◯

Due to SARS-COV-2 ◯

Other ◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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 ◯

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: ▩ (b) (4) ▩ **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

SAEID	USA-US059-2021-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: ▓▓ (b) (4) ▓▓ **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

SAEID	USA-US059-2021-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/JAN/2021 17:54
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

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

SAEID	USA-US059-2021-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/JAN/2021 22:34
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

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) **26 Apr 2021 22:46:32**

Generated On: 11 Aug 2021 22:33:31

SAEID	USA-US059-2021-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/MAR/2021 15:22
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

US3402196 (Prod: Meridian Clinical Research, LLC)

US3402196

Form: Participant Creation

Generated On: 11 Aug 2021 22:33:31

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
User entered 'US3402196'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 11:54:12

US3402196

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:49:57

US3402196

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 11:54:13

US3402196
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31

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 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:49:57

US3402196
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'SCRN'	System	03 Aug 2020 12:49:57

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 11:54:14

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '72'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

US3402196
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'YEARS'	System	03 Aug 2020 16:31:00

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered '72'	System	03 Aug 2020 12:50:15

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Male (M)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Traci Hull (b) (4)	03 Aug 2020 16:31:00
	(b) (4)	

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
	(b) (4)	
User entered '1'	Traci Hull (b) (4)	03 Aug 2020 16:31:00
	(b) (4)	

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

US3402196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

US3402196
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

US3402196
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:33:31
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:00

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '3 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:50:15

US3402196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'Aug 2020'	System	03 Aug 2020 12:50:15

US3402196
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered '2020'	System	03 Aug 2020 12:50:15

US3402196
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:33:31
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Amendment 1 (1)'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:50:15

US3402196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:50:15

US3402196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:50:15

US3402196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:50:15

US3402196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:50:15

US3402196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 11:54:13

US3402196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered '1'	System	03 Aug 2020 12:50:20

US3402196

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:33:31

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:50:20

US3402196
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:33:31
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:01

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 16:35:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 16:35:04
Data point term sent to Coder	System	03 Aug 2020 16:33:33
User entered 'hypertension'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'un UNK 1990'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4)	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'Jan 1990'	System	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered '1990'	System	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered empty.	System	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered empty.	System	03 Aug 2020 16:33:26

US3402196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 16:35:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 16:35:04
Data point term sent to Coder	System	03 Aug 2020 16:34:33
User entered 'hyperlipidemia'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:45

US3402196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'un UNK 1990'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:45

US3402196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:45

US3402196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 16:33:45

US3402196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:33:45

US3402196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'Jan 1990'	System	03 Aug 2020 16:33:45

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered '1990'	System	03 Aug 2020 16:33:45

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US3402196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered empty.	System	03 Aug 2020 16:33:45

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered empty.	System	03 Aug 2020 16:33:45

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '07:43'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered '3 Aug 2020 07:43'	System	03 Aug 2020 16:34:35

US3402196
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '166.5' cm	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35
DataPoint set to visible.	System	03 Aug 2020 12:50:20

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '94.8' kg	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35
DataPoint set to visible.	System	03 Aug 2020 12:50:20

US3402196
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
Amendment Manager: User entered '34.19636'	System	16 Sep 2020 23:40:50
User entered '34.2'	System	03 Aug 2020 16:34:35
DataPoint set to visible.	System	03 Aug 2020 12:50:20

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'kg/m2'	System	03 Aug 2020 16:34:35
DataPoint set to visible.	System	03 Aug 2020 12:50:20

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User closed query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, 'ND-NOT DONE' should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:33:28
Query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, 'ND-NOT DONE' should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' answered with 'DATA UPDATED TO ND' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 13:48:13
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Dec 2020 13:48:05
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Dec 2020 13:48:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 13:48:05
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Dec 2020 13:47:57
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 13:47:57
User opened query 'Per CDM: As per CCGs page 17-18, for Screening and Visit 1 on the same day, 'ND-NOT DONE' should be recorded for Temperature (without unit), Pulse, Respiratory rate, Systolic BP and Diastolic BP. Please update accordingly. Note: Route of measurement should be left blank' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:55:04
User entered '36.5' C	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 13:47:57
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

US3402196
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 13:47:57
User entered '72'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

US3402196
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'bpm'	System	03 Aug 2020 16:34:35

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 13:47:57
User entered '14'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'breaths/min'	System	03 Aug 2020 16:34:35

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 13:47:57
User entered '146'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

US3402196
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'mmHg'	System	03 Aug 2020 16:34:35

US3402196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 13:47:57
User entered '82'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:34:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User entered 'mmHg'	System	03 Aug 2020 16:34:35

Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13

US3402196
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13

Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:01

US3402196

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	06 Sep 2020 12:33:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 14:32:53
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:01

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'mechanic'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '1'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:33:31
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:25:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:31:42

US3402196

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:15

US3402196

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:15

US3402196
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:15

US3402196
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'VISIT1'	System	03 Aug 2020 16:35:15

US3402196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 11:54:15

US3402196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:41:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:41:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 11:54:15
User entered '184441' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 11:54:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 11:54:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:35:25

US3402196
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:02:17
User entered '166.5' cm	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

US3402196
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:02:17
User entered '94.8' kg	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:02:17
User entered '166.5' cm	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

US3402196
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:02:17
User entered '94.8' kg	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

US3402196
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

US3402196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '07:43'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '3 Aug 2020 07:43'	System	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '36.5' C	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '72'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'bpm'	System	03 Aug 2020 16:37:44

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '14'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

FDA-CBER-2022-1614-1736595

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'breaths/min'	System	03 Aug 2020 16:37:44

FDA-CBER-2022-1614-1736596

US3402196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '146'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'mmHg'	System	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '82'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'mmHg'	System	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:02:17
User entered '166.5' cm	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

US3402196
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 13:02:17
User entered '94.8' kg	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '09:43'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '3 Aug 2020 09:43'	System	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User closed query 'Per CDM: Per previous query, please confirm if this result should be considered clinically significant or not.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:18:18
Query 'Per CDM: Per previous query, please confirm if this result should be considered clinically significant or not.' answered with 'CORRECT AS IS. NOT CLINICALY SIGNIFICANT' (Site from DM).	Traci Hull (b) (4) (b) (4)	22 Sep 2020 20:03:57
User opened query 'Per CDM: Per previous query, please confirm if this result should be considered clinically significant or not.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:55:00
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 14:54:25
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as is' (Site from System).	Traci Hull (b) (4) (b) (4)	18 Sep 2020 12:35:05
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:40:50
User entered '96.4' F	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '63'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'bpm'	System	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '14'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'breaths/min'	System	03 Aug 2020 16:37:44

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '138'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'mmHg'	System	03 Aug 2020 16:37:44

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '80'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:44

FDA-CBER-2022-1614-1736617

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'mmHg'	System	03 Aug 2020 16:37:44

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	08 Sep 2020 20:01:15
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:56

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty; reason for change Data Entry Error	Traci Hull (b) (4) (b) (4)	08 Sep 2020 20:01:15
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:37:56

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:51:17

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:51:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:51:17

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 12:51:17

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '3 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:51:17

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '08:32'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:51:17

US3402196
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:33:31

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '3 Aug 2020 08:32'	System	03 Aug 2020 12:51:17

US3402196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4) (b) (4)	03 Aug 2020 12:51:17

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'ONCE'	System	03 Aug 2020 12:51:17

FDA-CBER-2022-1614-1736629

US3402196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 12:51:17

US3402196

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:18

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:18

US3402196

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '08:06'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:18

US3402196

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '3 Aug 2020 08:06'	System	03 Aug 2020 16:38:18

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:38

US3402196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:38

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '08:00'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:38

US3402196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '3 Aug 2020 08:00'	System	03 Aug 2020 16:38:38

US3402196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:38

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:38

US3402196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered empty.	System	03 Aug 2020 16:38:38

US3402196

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:38:47

US3402196
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	03 Aug 2020 16:38:47

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:05:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '942786a9-f82d-4ebb-b25d-d81f1d2975f6'	System	03 Aug 2020 13:05:52
User entered 'Yes (Y)'	System	03 Aug 2020 13:05:52

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:05:12', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '942786a9-f82d-4ebb-b25d-d81f1d2975f6'	System	03 Aug 2020 13:05:52
User entered '96.4'	System	03 Aug 2020 13:05:52

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:05:39', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '942786a9-f82d-4ebb-b25d-d81f1d2975f6'	System	03 Aug 2020 13:05:52
User entered 'No (N)'	System	03 Aug 2020 13:05:52

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:05:50', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '942786a9-f82d-4ebb-b25d-d81f1d2975f6'	System	03 Aug 2020 13:05:52
User entered '03 Aug 2020 09:05'	System	03 Aug 2020 13:05:52

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 08:52'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 11:22'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:52:45', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bf6c8388-47f0-4227-b95e-29d035d736a8'	System	03 Aug 2020 22:53:18
User entered 'Yes (Y)'	System	03 Aug 2020 22:53:18

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:52:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bf6c8388-47f0-4227-b95e-29d035d736a8'	System	03 Aug 2020 22:53:18
User entered '96.8'	System	03 Aug 2020 22:53:18

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:53:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bf6c8388-47f0-4227-b95e-29d035d736a8'	System	03 Aug 2020 22:53:18
User entered 'No (N)'	System	03 Aug 2020 22:53:18

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:53:17', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bf6c8388-47f0-4227-b95e-29d035d736a8'	System	03 Aug 2020 22:53:18
User entered '03 Aug 2020 18:53'	System	03 Aug 2020 22:53:18

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 12:17'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 2'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:09:03', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'edf7402d-25e7-476e-b568-2c04e86a815d'	System	04 Aug 2020 22:09:27
User entered 'Yes (Y)'	System	04 Aug 2020 22:09:27

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:09:12', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'edf7402d-25e7-476e-b568-2c04e86a815d'	System	04 Aug 2020 22:09:27
User entered '96.1'	System	04 Aug 2020 22:09:27

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:09:18', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'edf7402d-25e7-476e-b568-2c04e86a815d'	System	04 Aug 2020 22:09:27
User entered 'No (N)'	System	04 Aug 2020 22:09:27

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:09:25', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'edf7402d-25e7-476e-b568-2c04e86a815d'	System	04 Aug 2020 22:09:27
User entered '04 Aug 2020 18:09'	System	04 Aug 2020 22:09:27

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 3'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:02:19', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f3cb38c7-cabb-4870-bfed-fb71c447a408'	System	05 Aug 2020 22:02:41
User entered 'Yes (Y)'	System	05 Aug 2020 22:02:41

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:02:27', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f3cb38c7-cabb-4870-bfed-fb71c447a408'	System	05 Aug 2020 22:02:41
User entered '96.5'	System	05 Aug 2020 22:02:41

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:02:33', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f3cb38c7-cabb-4870-bfed-fb71c447a408'	System	05 Aug 2020 22:02:41
User entered 'No (N)'	System	05 Aug 2020 22:02:41

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:02:39', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f3cb38c7-cabb-4870-bfed-fb71c447a408'	System	05 Aug 2020 22:02:41
User entered '05 Aug 2020 18:02'	System	05 Aug 2020 22:02:41

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 4'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T17:59:06', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '88d7ea28-14bb-40f5-a6ed-9647982bbc64'	System	06 Aug 2020 21:59:46
User entered 'Yes (Y)'	System	06 Aug 2020 21:59:46

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T17:59:28', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '88d7ea28-14bb-40f5-a6ed-9647982bbc64'	System	06 Aug 2020 21:59:46
User entered '96.6'	System	06 Aug 2020 21:59:46

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T17:59:37', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '88d7ea28-14bb-40f5-a6ed-9647982bbc64'	System	06 Aug 2020 21:59:46
User entered 'No (N)'	System	06 Aug 2020 21:59:46

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T17:59:45', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '88d7ea28-14bb-40f5-a6ed-9647982bbc64'	System	06 Aug 2020 21:59:46
User entered '06 Aug 2020 17:59'	System	06 Aug 2020 21:59:46

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 5'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:03:47', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'cf32f0bf-6162-492a-843d-ffee5f8f48db'	System	07 Aug 2020 22:04:11
User entered 'Yes (Y)'	System	07 Aug 2020 22:04:11

FDA-CBER-2022-1614-1736682

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:03:56', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'cf32f0bf-6162-492a-843d-ffee5f8f48db'	System	07 Aug 2020 22:04:11
User entered '96.8'	System	07 Aug 2020 22:04:11

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:04:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'cf32f0bf-6162-492a-843d-ffee5f8f48db'	System	07 Aug 2020 22:04:11
User entered 'No (N)'	System	07 Aug 2020 22:04:11

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:04:08', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'cf32f0bf-6162-492a-843d-ffee5f8f48db'	System	07 Aug 2020 22:04:11
User entered '07 Aug 2020 18:04'	System	07 Aug 2020 22:04:11

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 6'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:05:40', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3f8a29d9-983e-49c5-b80b-703fee29e1d9'	System	08 Aug 2020 22:06:19
User entered 'Yes (Y)'	System	08 Aug 2020 22:06:19

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:05:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3f8a29d9-983e-49c5-b80b-703fee29e1d9'	System	08 Aug 2020 22:06:19
User entered '97.0'	System	08 Aug 2020 22:06:19

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:06:10', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3f8a29d9-983e-49c5-b80b-703fee29e1d9'	System	08 Aug 2020 22:06:19
User entered 'No (N)'	System	08 Aug 2020 22:06:19

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:06:18', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3f8a29d9-983e-49c5-b80b-703fee29e1d9'	System	08 Aug 2020 22:06:19
User entered '08 Aug 2020 18:06'	System	08 Aug 2020 22:06:19

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 7'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:43:12', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dc11c3f-d27e-4458-9e64-2b9b877d7fab'	System	09 Aug 2020 20:43:54
User entered 'Yes (Y)'	System	09 Aug 2020 20:43:54

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:43:33', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dc11c3f-d27e-4458-9e64-2b9b877d7fab'	System	09 Aug 2020 20:43:54
User entered '96.8'	System	09 Aug 2020 20:43:54

US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:43:43', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dc11c3f-d27e-4458-9e64-2b9b877d7fab'	System	09 Aug 2020 20:43:54
User entered 'No (N)'	System	09 Aug 2020 20:43:54

US3402196
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:43:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dc11c3f-d27e-4458-9e64-2b9b877d7fab'	System	09 Aug 2020 20:43:54
User entered '09 Aug 2020 16:43'	System	09 Aug 2020 20:43:54

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

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US3402196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:06:11', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '696541f4-6091-4115-b59a-951e119b8cd0'	System	03 Aug 2020 13:06:47
User entered 'None (1)'	System	03 Aug 2020 13:06:47

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:06:23', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '696541f4-6091-4115-b59a-951e119b8cd0'	System	03 Aug 2020 13:06:47
User entered 'No (N)'	System	03 Aug 2020 13:06:47

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:06:31', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '696541f4-6091-4115-b59a-951e119b8cd0'	System	03 Aug 2020 13:06:47
User entered 'No (N)'	System	03 Aug 2020 13:06:47

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:06:37', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '696541f4-6091-4115-b59a-951e119b8cd0'	System	03 Aug 2020 13:06:47
User entered 'None (1)'	System	03 Aug 2020 13:06:47

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:06:43', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '696541f4-6091-4115-b59a-951e119b8cd0'	System	03 Aug 2020 13:06:47
User entered '03 Aug 2020 09:06'	System	03 Aug 2020 13:06:47

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 08:52'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 11:22'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:53:30', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '87f83ad5-bfc0-4369-8b7d-c2e5d791d5a7'	System	03 Aug 2020 22:54:06
User entered 'None (1)'	System	03 Aug 2020 22:54:06

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:53:39', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '87f83ad5-bfc0-4369-8b7d-c2e5d791d5a7'	System	03 Aug 2020 22:54:06
User entered 'No (N)'	System	03 Aug 2020 22:54:06

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:53:47', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '87f83ad5-bfc0-4369-8b7d-c2e5d791d5a7'	System	03 Aug 2020 22:54:06
User entered 'No (N)'	System	03 Aug 2020 22:54:06

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:53:56', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '87f83ad5-bfc0-4369-8b7d-c2e5d791d5a7'	System	03 Aug 2020 22:54:06
User entered 'None (1)'	System	03 Aug 2020 22:54:06

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:02', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '87f83ad5-bfc0-4369-8b7d-c2e5d791d5a7'	System	03 Aug 2020 22:54:06
User entered '03 Aug 2020 18:54'	System	03 Aug 2020 22:54:06

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 12:17'	System	03 Aug 2020 12:51:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 2'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:09:36', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2fcbff3-12f9-4e04-90c3-8896d915e804'	System	04 Aug 2020 22:10:17
User entered 'None (1)'	System	04 Aug 2020 22:10:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:09:45', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2fcbff3-12f9-4e04-90c3-8896d915e804'	System	04 Aug 2020 22:10:17
User entered 'No (N)'	System	04 Aug 2020 22:10:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:09:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2fcbff3-12f9-4e04-90c3-8896d915e804'	System	04 Aug 2020 22:10:17
User entered 'No (N)'	System	04 Aug 2020 22:10:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:09', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2fcbff3-12f9-4e04-90c3-8896d915e804'	System	04 Aug 2020 22:10:17
User entered 'None (1)'	System	04 Aug 2020 22:10:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:15', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2fcbff3-12f9-4e04-90c3-8896d915e804'	System	04 Aug 2020 22:10:17
User entered '04 Aug 2020 18:10'	System	04 Aug 2020 22:10:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 3'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:02:46', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '56ef007a-61a1-449f-9b17-6ea36461723c'	System	05 Aug 2020 22:03:31
User entered 'None (1)'	System	05 Aug 2020 22:03:31

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:02:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '56ef007a-61a1-449f-9b17-6ea36461723c'	System	05 Aug 2020 22:03:31
User entered 'No (N)'	System	05 Aug 2020 22:03:31

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:03:07', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '56ef007a-61a1-449f-9b17-6ea36461723c'	System	05 Aug 2020 22:03:31
User entered 'No (N)'	System	05 Aug 2020 22:03:31

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:03:24', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '56ef007a-61a1-449f-9b17-6ea36461723c'	System	05 Aug 2020 22:03:31
User entered 'None (1)'	System	05 Aug 2020 22:03:31

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:03:29', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '56ef007a-61a1-449f-9b17-6ea36461723c'	System	05 Aug 2020 22:03:31
User entered '05 Aug 2020 18:03'	System	05 Aug 2020 22:03:31

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 4'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T17:59:55', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bafd4ed2-28a8-48b6-a90a-590980c97b59'	System	06 Aug 2020 22:00:26
User entered 'None (1)'	System	06 Aug 2020 22:00:26

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T17:59:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bafd4ed2-28a8-48b6-a90a-590980c97b59'	System	06 Aug 2020 22:00:26
User entered 'No (N)'	System	06 Aug 2020 22:00:26

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:08', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bafd4ed2-28a8-48b6-a90a-590980c97b59'	System	06 Aug 2020 22:00:26
User entered 'No (N)'	System	06 Aug 2020 22:00:26

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:17', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bafd4ed2-28a8-48b6-a90a-590980c97b59'	System	06 Aug 2020 22:00:26
User entered 'None (1)'	System	06 Aug 2020 22:00:26

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:21', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bafd4ed2-28a8-48b6-a90a-590980c97b59'	System	06 Aug 2020 22:00:26
User entered '06 Aug 2020 18:00'	System	06 Aug 2020 22:00:26

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 5'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:04:30', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f8b74c14-b624-43bf-8753-39c632bb0177'	System	07 Aug 2020 22:04:53
User entered 'None (1)'	System	07 Aug 2020 22:04:53

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:04:36', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f8b74c14-b624-43bf-8753-39c632bb0177'	System	07 Aug 2020 22:04:53
User entered 'No (N)'	System	07 Aug 2020 22:04:53

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:04:41', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f8b74c14-b624-43bf-8753-39c632bb0177'	System	07 Aug 2020 22:04:53
User entered 'No (N)'	System	07 Aug 2020 22:04:53

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:04:48', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f8b74c14-b624-43bf-8753-39c632bb0177'	System	07 Aug 2020 22:04:53
User entered 'None (1)'	System	07 Aug 2020 22:04:53

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:04:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f8b74c14-b624-43bf-8753-39c632bb0177'	System	07 Aug 2020 22:04:53
User entered '07 Aug 2020 18:04'	System	07 Aug 2020 22:04:53

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 6'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:06:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd550e2e2-3960-495f-8bca-eaeb60049d45'	System	08 Aug 2020 22:07:32
User entered 'None (1)'	System	08 Aug 2020 22:07:32

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:06:51', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd550e2e2-3960-495f-8bca-eaeb60049d45'	System	08 Aug 2020 22:07:32
User entered 'No (N)'	System	08 Aug 2020 22:07:32

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:06:56', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd550e2e2-3960-495f-8bca-eaeb60049d45'	System	08 Aug 2020 22:07:32
User entered 'No (N)'	System	08 Aug 2020 22:07:32

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:07:24', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd550e2e2-3960-495f-8bca-eaeb60049d45'	System	08 Aug 2020 22:07:32
User entered 'None (1)'	System	08 Aug 2020 22:07:32

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:07:28', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd550e2e2-3960-495f-8bca-eaeb60049d45'	System	08 Aug 2020 22:07:32
User entered '08 Aug 2020 18:07'	System	08 Aug 2020 22:07:32

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 7'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:44:03', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4347d23b-69cd-4183-8329-b8e9d618c785'	System	09 Aug 2020 20:44:34
User entered 'None (1)'	System	09 Aug 2020 20:44:34

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:44:10', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4347d23b-69cd-4183-8329-b8e9d618c785'	System	09 Aug 2020 20:44:34
User entered 'No (N)'	System	09 Aug 2020 20:44:34

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:44:15', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4347d23b-69cd-4183-8329-b8e9d618c785'	System	09 Aug 2020 20:44:34
User entered 'No (N)'	System	09 Aug 2020 20:44:34

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:44:18', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4347d23b-69cd-4183-8329-b8e9d618c785'	System	09 Aug 2020 20:44:34
User entered 'None (1)'	System	09 Aug 2020 20:44:34

US3402196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:44:32', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4347d23b-69cd-4183-8329-b8e9d618c785'	System	09 Aug 2020 20:44:34
User entered '09 Aug 2020 16:44'	System	09 Aug 2020 20:44:34

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:07:05', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '0831b257-8c4f-4614-8e7d-1ed4c1c2b328'	System	03 Aug 2020 13:07:53
User entered 'None (0)'	System	03 Aug 2020 13:07:53

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:07:11', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '0831b257-8c4f-4614-8e7d-1ed4c1c2b328'	System	03 Aug 2020 13:07:53
User entered 'None (0)'	System	03 Aug 2020 13:07:53

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:07:15', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '0831b257-8c4f-4614-8e7d-1ed4c1c2b328'	System	03 Aug 2020 13:07:53
User entered 'None (0)'	System	03 Aug 2020 13:07:53

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:07:22', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '0831b257-8c4f-4614-8e7d-1ed4c1c2b328'	System	03 Aug 2020 13:07:53
User entered 'None (0)'	System	03 Aug 2020 13:07:53

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:07:27', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '0831b257-8c4f-4614-8e7d-1ed4c1c2b328'	System	03 Aug 2020 13:07:53
User entered 'None (0)'	System	03 Aug 2020 13:07:53

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:07:34', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '0831b257-8c4f-4614-8e7d-1ed4c1c2b328'	System	03 Aug 2020 13:07:53
User entered 'None (0)'	System	03 Aug 2020 13:07:53

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:07:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '0831b257-8c4f-4614-8e7d-1ed4c1c2b328'	System	03 Aug 2020 13:07:53
User entered 'No (N)'	System	03 Aug 2020 13:07:53

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T09:07:49', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '0831b257-8c4f-4614-8e7d-1ed4c1c2b328'	System	03 Aug 2020 13:07:53
User entered '03 Aug 2020 09:07'	System	03 Aug 2020 13:07:53

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 08:52'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 11:22'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:12', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd03ef27-5195-4f5f-b875-b482cc2aaa11'	System	03 Aug 2020 22:54:55
User entered 'None (0)'	System	03 Aug 2020 22:54:55

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:18', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd03ef27-5195-4f5f-b875-b482cc2aaa11'	System	03 Aug 2020 22:54:55
User entered 'None (0)'	System	03 Aug 2020 22:54:55

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:22', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd03ef27-5195-4f5f-b875-b482cc2aaa11'	System	03 Aug 2020 22:54:55
User entered 'None (0)'	System	03 Aug 2020 22:54:55

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:28', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd03ef27-5195-4f5f-b875-b482cc2aaa11'	System	03 Aug 2020 22:54:55
User entered 'None (0)'	System	03 Aug 2020 22:54:55

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:33', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd03ef27-5195-4f5f-b875-b482cc2aaa11'	System	03 Aug 2020 22:54:55
User entered 'None (0)'	System	03 Aug 2020 22:54:55

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:41', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd03ef27-5195-4f5f-b875-b482cc2aaa11'	System	03 Aug 2020 22:54:55
User entered 'None (0)'	System	03 Aug 2020 22:54:55

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:49', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd03ef27-5195-4f5f-b875-b482cc2aaa11'	System	03 Aug 2020 22:54:55
User entered 'No (N)'	System	03 Aug 2020 22:54:55

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-03T18:54:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd03ef27-5195-4f5f-b875-b482cc2aaa11'	System	03 Aug 2020 22:54:55
User entered '03 Aug 2020 18:54'	System	03 Aug 2020 22:54:55

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Aug 2020 12:17'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 2'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:23', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1fa916fa-b49b-4878-87da-64b52f105c65'	System	04 Aug 2020 22:11:09
User entered 'None (0)'	System	04 Aug 2020 22:11:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:30', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1fa916fa-b49b-4878-87da-64b52f105c65'	System	04 Aug 2020 22:11:09
User entered 'None (0)'	System	04 Aug 2020 22:11:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:35', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1fa916fa-b49b-4878-87da-64b52f105c65'	System	04 Aug 2020 22:11:09
User entered 'None (0)'	System	04 Aug 2020 22:11:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:41', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1fa916fa-b49b-4878-87da-64b52f105c65'	System	04 Aug 2020 22:11:09
User entered 'None (0)'	System	04 Aug 2020 22:11:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:46', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1fa916fa-b49b-4878-87da-64b52f105c65'	System	04 Aug 2020 22:11:09
User entered 'None (0)'	System	04 Aug 2020 22:11:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:50', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1fa916fa-b49b-4878-87da-64b52f105c65'	System	04 Aug 2020 22:11:09
User entered 'None (0)'	System	04 Aug 2020 22:11:09

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:10:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1fa916fa-b49b-4878-87da-64b52f105c65'	System	04 Aug 2020 22:11:09
User entered 'No (N)'	System	04 Aug 2020 22:11:09

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-04T18:11:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1fa916fa-b49b-4878-87da-64b52f105c65'	System	04 Aug 2020 22:11:09
User entered '04 Aug 2020 18:11'	System	04 Aug 2020 22:11:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 3'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:03:38', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '57c1d240-42a6-41b9-8432-0d1ff22ed98c'	System	05 Aug 2020 22:04:19
User entered 'None (0)'	System	05 Aug 2020 22:04:19

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:03:45', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '57c1d240-42a6-41b9-8432-0d1ff22ed98c'	System	05 Aug 2020 22:04:19
User entered 'None (0)'	System	05 Aug 2020 22:04:19

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:03:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '57c1d240-42a6-41b9-8432-0d1ff22ed98c'	System	05 Aug 2020 22:04:19
User entered 'None (0)'	System	05 Aug 2020 22:04:19

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:03:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '57c1d240-42a6-41b9-8432-0d1ff22ed98c'	System	05 Aug 2020 22:04:19
User entered 'None (0)'	System	05 Aug 2020 22:04:19

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:04:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '57c1d240-42a6-41b9-8432-0d1ff22ed98c'	System	05 Aug 2020 22:04:19
User entered 'None (0)'	System	05 Aug 2020 22:04:19

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:04:08', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '57c1d240-42a6-41b9-8432-0d1ff22ed98c'	System	05 Aug 2020 22:04:19
User entered 'None (0)'	System	05 Aug 2020 22:04:19

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:04:14', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '57c1d240-42a6-41b9-8432-0d1ff22ed98c'	System	05 Aug 2020 22:04:19
User entered 'No (N)'	System	05 Aug 2020 22:04:19

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-05T18:04:17', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '57c1d240-42a6-41b9-8432-0d1ff22ed98c'	System	05 Aug 2020 22:04:19
User entered '05 Aug 2020 18:04'	System	05 Aug 2020 22:04:19

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 4'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:33', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6b7f55a5-e1c9-491d-83e3-6b81537719b7'	System	06 Aug 2020 22:01:10
User entered 'None (0)'	System	06 Aug 2020 22:01:10

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:37', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6b7f55a5-e1c9-491d-83e3-6b81537719b7'	System	06 Aug 2020 22:01:10
User entered 'None (0)'	System	06 Aug 2020 22:01:10

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:43', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6b7f55a5-e1c9-491d-83e3-6b81537719b7'	System	06 Aug 2020 22:01:10
User entered 'None (0)'	System	06 Aug 2020 22:01:10

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:49', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6b7f55a5-e1c9-491d-83e3-6b81537719b7'	System	06 Aug 2020 22:01:10
User entered 'None (0)'	System	06 Aug 2020 22:01:10

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:55', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6b7f55a5-e1c9-491d-83e3-6b81537719b7'	System	06 Aug 2020 22:01:10
User entered 'None (0)'	System	06 Aug 2020 22:01:10

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:00:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6b7f55a5-e1c9-491d-83e3-6b81537719b7'	System	06 Aug 2020 22:01:10
User entered 'None (0)'	System	06 Aug 2020 22:01:10

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:01:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6b7f55a5-e1c9-491d-83e3-6b81537719b7'	System	06 Aug 2020 22:01:10
User entered 'No (N)'	System	06 Aug 2020 22:01:10

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-06T18:01:07', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6b7f55a5-e1c9-491d-83e3-6b81537719b7'	System	06 Aug 2020 22:01:10
User entered '06 Aug 2020 18:01'	System	06 Aug 2020 22:01:10

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 5'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:05:02', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '952fa916-2161-4dff-9cd6-14ec5cdbde54'	System	07 Aug 2020 22:05:36
User entered 'None (0)'	System	07 Aug 2020 22:05:36

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:05:05', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '952fa916-2161-4dff-9cd6-14ec5cdbde54'	System	07 Aug 2020 22:05:36
User entered 'None (0)'	System	07 Aug 2020 22:05:36

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:05:10', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '952fa916-2161-4dff-9cd6-14ec5cdbde54'	System	07 Aug 2020 22:05:36
User entered 'None (0)'	System	07 Aug 2020 22:05:36

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:05:14', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '952fa916-2161-4dff-9cd6-14ec5cdbde54'	System	07 Aug 2020 22:05:36
User entered 'None (0)'	System	07 Aug 2020 22:05:36

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:05:18', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '952fa916-2161-4dff-9cd6-14ec5cdbde54'	System	07 Aug 2020 22:05:36
User entered 'None (0)'	System	07 Aug 2020 22:05:36

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:05:22', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '952fa916-2161-4dff-9cd6-14ec5cdbde54'	System	07 Aug 2020 22:05:36
User entered 'None (0)'	System	07 Aug 2020 22:05:36

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:05:27', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '952fa916-2161-4dff-9cd6-14ec5cdbde54'	System	07 Aug 2020 22:05:36
User entered 'No (N)'	System	07 Aug 2020 22:05:36

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US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-07T18:05:30', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '952fa916-2161-4dff-9cd6-14ec5cdbde54'	System	07 Aug 2020 22:05:36
User entered '07 Aug 2020 18:05'	System	07 Aug 2020 22:05:36

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 6'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:07:37', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '179a6899-3aea-4f04-b781-79863d257f36'	System	08 Aug 2020 22:08:09
User entered 'None (0)'	System	08 Aug 2020 22:08:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:07:41', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '179a6899-3aea-4f04-b781-79863d257f36'	System	08 Aug 2020 22:08:09
User entered 'None (0)'	System	08 Aug 2020 22:08:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:07:46', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '179a6899-3aea-4f04-b781-79863d257f36'	System	08 Aug 2020 22:08:09
User entered 'None (0)'	System	08 Aug 2020 22:08:09

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:07:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '179a6899-3aea-4f04-b781-79863d257f36'	System	08 Aug 2020 22:08:09
User entered 'None (0)'	System	08 Aug 2020 22:08:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:07:56', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '179a6899-3aea-4f04-b781-79863d257f36'	System	08 Aug 2020 22:08:09
User entered 'None (0)'	System	08 Aug 2020 22:08:09

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:07:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '179a6899-3aea-4f04-b781-79863d257f36'	System	08 Aug 2020 22:08:09
User entered 'None (0)'	System	08 Aug 2020 22:08:09

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:08:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '179a6899-3aea-4f04-b781-79863d257f36'	System	08 Aug 2020 22:08:09
User entered 'No (N)'	System	08 Aug 2020 22:08:09

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-08T18:08:08', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '179a6899-3aea-4f04-b781-79863d257f36'	System	08 Aug 2020 22:08:09
User entered '08 Aug 2020 18:08'	System	08 Aug 2020 22:08:09

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 7'	System	03 Aug 2020 12:51:17

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:44:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ccdecc88-13ee-4bdb-8a5f-eee63b65a992'	System	09 Aug 2020 20:45:32
User entered 'None (0)'	System	09 Aug 2020 20:45:32

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:45:06', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ccdecc88-13ee-4bdb-8a5f-eee63b65a992'	System	09 Aug 2020 20:45:32
User entered 'None (0)'	System	09 Aug 2020 20:45:32

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:45:11', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ccdecc88-13ee-4bdb-8a5f-eee63b65a992'	System	09 Aug 2020 20:45:32
User entered 'None (0)'	System	09 Aug 2020 20:45:32

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:45:14', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ccdecc88-13ee-4bdb-8a5f-eee63b65a992'	System	09 Aug 2020 20:45:32
User entered 'None (0)'	System	09 Aug 2020 20:45:32

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:45:18', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ccdecc88-13ee-4bdb-8a5f-eee63b65a992'	System	09 Aug 2020 20:45:32
User entered 'None (0)'	System	09 Aug 2020 20:45:32

US3402196
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:45:22', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ccdecc88-13ee-4bdb-8a5f-eee63b65a992'	System	09 Aug 2020 20:45:32
User entered 'None (0)'	System	09 Aug 2020 20:45:32

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:45:27', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ccdecc88-13ee-4bdb-8a5f-eee63b65a992'	System	09 Aug 2020 20:45:32
User entered 'No (N)'	System	09 Aug 2020 20:45:32

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-09T16:45:31', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ccdecc88-13ee-4bdb-8a5f-eee63b65a992'	System	09 Aug 2020 20:45:32
User entered '09 Aug 2020 16:45'	System	09 Aug 2020 20:45:32

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 12:51:17

US3402196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 17:11:21

US3402196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '10 Aug 2020'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 17:11:21

US3402196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 17:11:21

US3402196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Aug 2020 17:11:21

US3402196

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 17:11:27

US3402196
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	11 Aug 2020 17:11:27

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 18:46:46

FDA-CBER-2022-1614-1736860

US3402196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '17 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 18:46:46

US3402196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 18:46:46

US3402196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 18:46:46

US3402196

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 18:46:52

US3402196
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	17 Aug 2020 18:46:52

US3402196
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 11:38:24

US3402196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '24 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 11:38:24

US3402196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 11:38:24

US3402196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Aug 2020 11:38:24

US3402196

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 11:38:28

US3402196
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	26 Aug 2020 11:38:28

US3402196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:32:53

US3402196
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:32:53

US3402196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:32:53

US3402196
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'VISIT2'	System	31 Aug 2020 14:32:53

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 18:41:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 18:41:16
User entered 'Yes (Y)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:41:16
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 18:40:06
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:40:06
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '31 Aug 2020' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:41:16
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:40:06
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '07:26' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:41:16
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:40:06
User entered '07:26'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '31 Aug 2020 07:26'	System	02 Oct 2020 18:41:16
User entered empty.	System	02 Oct 2020 18:40:06
User entered '31 Aug 2020 07:26'	System	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '36.7' C reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:41:16
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:40:06
User entered '36.7' C	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Oral (Oral)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:41:16
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:40:06
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '78' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:41:16
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:40:06
User entered '78'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'bpm'	System	02 Oct 2020 18:41:16
User entered empty.	System	02 Oct 2020 18:40:06
User entered 'bpm'	System	31 Aug 2020 14:35:19

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '16' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:41:16
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:40:06
User entered '16'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'breaths/min'	System	02 Oct 2020 18:41:16
User entered empty.	System	02 Oct 2020 18:40:06
User entered 'breaths/min'	System	31 Aug 2020 14:35:19

FDA-CBER-2022-1614-1736887

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User closed query 'CDM RQ: Per previous response indicating results are CS, please update the Adverse Events form as appropriate or provide explanation.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:42:49
Query 'CDM RQ: Per previous response indicating results are CS, please update the Adverse Events form as appropriate or provide explanation.' answered with 'NO CS/NCS OR AE PATIENTS BLOOD PRESSURE HAS GONE BACK TO NORMAL' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 14:29:25
User opened query 'CDM RQ: Per previous response indicating results are CS, please update the Adverse Events form as appropriate or provide explanation.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 13:44:12
User closed query 'Per CDM: Response noted. Please confirm if this result should be considered Clinically Significant or not.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 13:44:12
Query 'Per CDM: Response noted. Please confirm if this result should be considered Clinically Significant or not.' answered with 'ABNORMAL, CS. SUBJECT WILL CALL PCP WITH READINGS' (Site from DM).	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:42:33
User entered '190' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:41:16
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:40:06
User opened query 'Per CDM: Response noted. Please confirm if this result should be considered Clinically Significant or not.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:07:50
User closed query 'Per CDM: Per previous query, please confirm if this should be considered CS or NCS and report as AE if appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:07:50
Query 'Per CDM: Per previous query, please confirm if this should be considered CS or NCS and report as AE if appropriate.' answered with 'correct as is' (Site from DM).	Traci Hull (b) (4) (b) (4)	18 Sep 2020 12:38:44

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User opened query 'Per CDM: Per previous query, please confirm if this should be considered CS or NCS and report as AE if appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:56:42
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)	01 Sep 2020 08:55:36
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 'correct as is' (Site from System).	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:36:35
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	31 Aug 2020 14:35:19
User entered '190'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'mmHg'	System	02 Oct 2020 18:41:16
User entered empty.	System	02 Oct 2020 18:40:06
User entered 'mmHg'	System	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '92'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:35:19

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'mmHg'	System	31 Aug 2020 14:35:19

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '08:39'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '31 Aug 2020 08:39'	System	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

US3402196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '69'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

US3402196
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'bpm'	System	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '16'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'breaths/min'	System	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User closed query 'CDM RQ: Per previous response indicating results are CS, please update the Adverse Events form as appropriate or provide explanation.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:43:14
Query 'CDM RQ: Per previous response indicating results are CS, please update the Adverse Events form as appropriate or provide explanation.' answered with 'NO CS/NCS OR AE. PATIENTS BLOOD PRESSURE RUNS HIGH FROM TIME TO TIME AND HAS RETURNED BACK TO NORMAL NOW THAT HE IS TAKING HIS MEDICATION AS DIRECTED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Oct 2020 14:30:33
User opened query 'CDM RQ: Per previous response indicating results are CS, please update the Adverse Events form as appropriate or provide explanation.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 13:44:45
User closed query 'Per CDM: Response noted. Please confirm if this result should be considered Clinically Significant or not.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 13:44:45
Query 'Per CDM: Response noted. Please confirm if this result should be considered Clinically Significant or not.' answered with 'ABNORMAL, CS. SUBJECT WILL CALL PCP WITH READINGS' (Site from DM).	Traci Hull (b) (4) (b) (4)	02 Oct 2020 18:43:31
User opened query 'Per CDM: Response noted. Please confirm if this result should be considered Clinically Significant or not.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:08:28
User closed query 'Per CDM: Per previous query, please confirm if this should be considered CS or NCS and report as AE if appropriate' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:08:28
Query 'Per CDM: Per previous query, please confirm if this should be considered CS or NCS and report as AE if appropriate' answered with 'correct as is' (Site from DM).	Traci Hull (b) (4) (b) (4)	18 Sep 2020 12:39:33
User opened query 'Per CDM: Per previous query, please confirm if this should be considered CS or NCS and report as AE if appropriate' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:57:12

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
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)	01 Sep 2020 08:57:04
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 'correct as is' (Site from System).	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:21
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	31 Aug 2020 14:37:11
User entered '190'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'mmHg'	System	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '85'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:11

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'mmHg'	System	31 Aug 2020 14:37:11

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:33

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:33

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	31 Aug 2020 12:17:13

US3402196
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Tarin Gordon (b) (4) (b) (4)	31 Aug 2020 12:17:13

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Tarin Gordon (b) (4) (b) (4)	31 Aug 2020 12:17:13

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 12:17:13

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '31 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	31 Aug 2020 12:17:13

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '08:08'	Tarin Gordon (b) (4) (b) (4)	31 Aug 2020 12:17:13

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '31 Aug 2020 08:08'	System	31 Aug 2020 12:17:13

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Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4) (b) (4)	31 Aug 2020 12:17:13

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'ONCE'	System	31 Aug 2020 12:17:13

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Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 12:17:13

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:50

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:50

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '07:55'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:37:50

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '31 Aug 2020 07:55'	System	31 Aug 2020 14:37:50

US3402196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:38:02

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:38:02

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:38:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '07:48'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:38:02

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '31 Aug 2020 07:48'	System	31 Aug 2020 14:38:02

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:38:02

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:38:02

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:38:02

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered empty.	System	31 Aug 2020 14:38:02

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Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 14:38:07

US3402196
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	31 Aug 2020 14:38:07

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:56:48', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4662cf29-74e2-4893-afef-804e80dcf35c'	System	31 Aug 2020 12:57:14
User entered 'Yes (Y)'	System	31 Aug 2020 12:57:14

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:56:57', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4662cf29-74e2-4893-afef-804e80dcf35c'	System	31 Aug 2020 12:57:14
User entered '97.8'	System	31 Aug 2020 12:57:14

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:57:06', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4662cf29-74e2-4893-afef-804e80dcf35c'	System	31 Aug 2020 12:57:14
User entered 'No (N)'	System	31 Aug 2020 12:57:14

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:57:12', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '4662cf29-74e2-4893-afef-804e80dcf35c'	System	31 Aug 2020 12:57:14
User entered '31 Aug 2020 08:57'	System	31 Aug 2020 12:57:14

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 08:28'	System	31 Aug 2020 12:17:13

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 10:58'	System	31 Aug 2020 12:17:13

FDA-CBER-2022-1614-1736943

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:03:21', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e42d900e-c861-478f-945d-25bb62eb1b87'	System	31 Aug 2020 23:03:46
User entered 'Yes (Y)'	System	31 Aug 2020 23:03:46

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:03:32', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e42d900e-c861-478f-945d-25bb62eb1b87'	System	31 Aug 2020 23:03:46
User entered '97.9'	System	31 Aug 2020 23:03:46

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:03:39', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e42d900e-c861-478f-945d-25bb62eb1b87'	System	31 Aug 2020 23:03:46
User entered 'No (N)'	System	31 Aug 2020 23:03:46

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:03:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e42d900e-c861-478f-945d-25bb62eb1b87'	System	31 Aug 2020 23:03:46
User entered '31 Aug 2020 19:03'	System	31 Aug 2020 23:03:46

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 11:53'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 2'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:54:35', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4751df1-c800-4b71-95a8-7cdb8d67edeb'	System	01 Sep 2020 20:55:27
User entered 'Yes (Y)'	System	01 Sep 2020 20:55:27

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:55:12', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4751df1-c800-4b71-95a8-7cdb8d67edeb'	System	01 Sep 2020 20:55:27
User entered '97.6'	System	01 Sep 2020 20:55:27

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:55:17', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4751df1-c800-4b71-95a8-7cdb8d67edeb'	System	01 Sep 2020 20:55:27
User entered 'No (N)'	System	01 Sep 2020 20:55:27

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:55:24', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4751df1-c800-4b71-95a8-7cdb8d67edeb'	System	01 Sep 2020 20:55:27
User entered '01 Sep 2020 16:55'	System	01 Sep 2020 20:55:27

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 3'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:04:38', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e386cdbd-6d3a-453d-9f58-4572e37ca1f6'	System	02 Sep 2020 23:05:04
User entered 'Yes (Y)'	System	02 Sep 2020 23:05:04

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:04:48', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e386cdbd-6d3a-453d-9f58-4572e37ca1f6'	System	02 Sep 2020 23:05:04
User entered '96.8'	System	02 Sep 2020 23:05:04

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:04:55', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e386cdbd-6d3a-453d-9f58-4572e37ca1f6'	System	02 Sep 2020 23:05:04
User entered 'No (N)'	System	02 Sep 2020 23:05:04

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e386cdbd-6d3a-453d-9f58-4572e37ca1f6'	System	02 Sep 2020 23:05:04
User entered '02 Sep 2020 19:05'	System	02 Sep 2020 23:05:04

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 4'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:17:37', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8f64ea9d-2ed7-4c85-a2bb-62278be26a9d'	System	04 Sep 2020 00:18:37
User entered 'Yes (Y)'	System	04 Sep 2020 00:18:37

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:18:20', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8f64ea9d-2ed7-4c85-a2bb-62278be26a9d'	System	04 Sep 2020 00:18:37
User entered '97.2'	System	04 Sep 2020 00:18:37

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:18:25', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8f64ea9d-2ed7-4c85-a2bb-62278be26a9d'	System	04 Sep 2020 00:18:37
User entered 'No (N)'	System	04 Sep 2020 00:18:37

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:18:31', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8f64ea9d-2ed7-4c85-a2bb-62278be26a9d'	System	04 Sep 2020 00:18:37
User entered '03 Sep 2020 20:18'	System	04 Sep 2020 00:18:37

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

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US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 5'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:57:47', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '7f636e46-294f-4185-9b4b-d19205bebe34'	System	04 Sep 2020 21:58:07
User entered 'Yes (Y)'	System	04 Sep 2020 21:58:07

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:57:55', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '7f636e46-294f-4185-9b4b-d19205bebe34'	System	04 Sep 2020 21:58:07
User entered '97.2'	System	04 Sep 2020 21:58:07

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '7f636e46-294f-4185-9b4b-d19205bebe34'	System	04 Sep 2020 21:58:07
User entered 'No (N)'	System	04 Sep 2020 21:58:07

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '7f636e46-294f-4185-9b4b-d19205bebe34'	System	04 Sep 2020 21:58:07
User entered '04 Sep 2020 17:58'	System	04 Sep 2020 21:58:07

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 6'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:52:14', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8f91611a-d71e-402e-a000-92e0d607692c'	System	05 Sep 2020 21:52:38
User entered 'Yes (Y)'	System	05 Sep 2020 21:52:38

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:52:27', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8f91611a-d71e-402e-a000-92e0d607692c'	System	05 Sep 2020 21:52:38
User entered '97.6'	System	05 Sep 2020 21:52:38

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:52:31', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8f91611a-d71e-402e-a000-92e0d607692c'	System	05 Sep 2020 21:52:38
User entered 'No (N)'	System	05 Sep 2020 21:52:38

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US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:52:35', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8f91611a-d71e-402e-a000-92e0d607692c'	System	05 Sep 2020 21:52:38
User entered '05 Sep 2020 17:52'	System	05 Sep 2020 21:52:38

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 7'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:50:38', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '113c54b3-a8ec-428d-ad2f-1bd80b5ace3d'	System	06 Sep 2020 20:51:49
User entered 'Yes (Y)'	System	06 Sep 2020 20:51:49

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:51:36', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '113c54b3-a8ec-428d-ad2f-1bd80b5ace3d'	System	06 Sep 2020 20:51:49
User entered '97.5'	System	06 Sep 2020 20:51:49

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:51:43', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '113c54b3-a8ec-428d-ad2f-1bd80b5ace3d'	System	06 Sep 2020 20:51:49
User entered 'No (N)'	System	06 Sep 2020 20:51:49

US3402196

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:51:48', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '113c54b3-a8ec-428d-ad2f-1bd80b5ace3d'	System	06 Sep 2020 20:51:49
User entered '06 Sep 2020 16:51'	System	06 Sep 2020 20:51:49

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:57:29', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8abe4842-1891-4e44-8485-1a4c2f0d03c5'	System	31 Aug 2020 12:57:51
User entered 'None (1)'	System	31 Aug 2020 12:57:51

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:57:34', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8abe4842-1891-4e44-8485-1a4c2f0d03c5'	System	31 Aug 2020 12:57:51
User entered 'No (N)'	System	31 Aug 2020 12:57:51

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:57:37', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8abe4842-1891-4e44-8485-1a4c2f0d03c5'	System	31 Aug 2020 12:57:51
User entered 'No (N)'	System	31 Aug 2020 12:57:51

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:57:41', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8abe4842-1891-4e44-8485-1a4c2f0d03c5'	System	31 Aug 2020 12:57:51
User entered 'None (1)'	System	31 Aug 2020 12:57:51

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:57:46', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8abe4842-1891-4e44-8485-1a4c2f0d03c5'	System	31 Aug 2020 12:57:51
User entered '31 Aug 2020 08:57'	System	31 Aug 2020 12:57:51

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 08:28'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 10:58'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:03:54', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4391d1e-e8c5-46d6-b709-a40d817043b2'	System	31 Aug 2020 23:04:53
User entered 'None (1)'	System	31 Aug 2020 23:04:53

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:04:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4391d1e-e8c5-46d6-b709-a40d817043b2'	System	31 Aug 2020 23:04:53
User entered 'No (N)'	System	31 Aug 2020 23:04:53

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:04:21', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4391d1e-e8c5-46d6-b709-a40d817043b2'	System	31 Aug 2020 23:04:53
User entered 'No (N)'	System	31 Aug 2020 23:04:53

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:04:43', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4391d1e-e8c5-46d6-b709-a40d817043b2'	System	31 Aug 2020 23:04:53
User entered 'None (1)'	System	31 Aug 2020 23:04:53

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:04:47', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd4391d1e-e8c5-46d6-b709-a40d817043b2'	System	31 Aug 2020 23:04:53
User entered '31 Aug 2020 19:04'	System	31 Aug 2020 23:04:53

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 11:53'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 2'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:55:41', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e1c1e7d1-0ee5-46c3-8a68-8ce2bae1a29b'	System	01 Sep 2020 20:56:14
User entered 'None (1)'	System	01 Sep 2020 20:56:14

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:55:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e1c1e7d1-0ee5-46c3-8a68-8ce2bae1a29b'	System	01 Sep 2020 20:56:14
User entered 'No (N)'	System	01 Sep 2020 20:56:14

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:55:57', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e1c1e7d1-0ee5-46c3-8a68-8ce2bae1a29b'	System	01 Sep 2020 20:56:14
User entered 'No (N)'	System	01 Sep 2020 20:56:14

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US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:06', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e1c1e7d1-0ee5-46c3-8a68-8ce2bae1a29b'	System	01 Sep 2020 20:56:14
User entered 'None (1)'	System	01 Sep 2020 20:56:14

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:11', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e1c1e7d1-0ee5-46c3-8a68-8ce2bae1a29b'	System	01 Sep 2020 20:56:14
User entered '01 Sep 2020 16:56'	System	01 Sep 2020 20:56:14

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 3'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:21', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e542beb7-1dc0-4d79-9fd2-5b8b5dd8606d'	System	02 Sep 2020 23:05:43
User entered 'None (1)'	System	02 Sep 2020 23:05:43

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:27', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e542beb7-1dc0-4d79-9fd2-5b8b5dd8606d'	System	02 Sep 2020 23:05:43
User entered 'No (N)'	System	02 Sep 2020 23:05:43

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:31', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e542beb7-1dc0-4d79-9fd2-5b8b5dd8606d'	System	02 Sep 2020 23:05:43
User entered 'No (N)'	System	02 Sep 2020 23:05:43

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:36', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e542beb7-1dc0-4d79-9fd2-5b8b5dd8606d'	System	02 Sep 2020 23:05:43
User entered 'None (1)'	System	02 Sep 2020 23:05:43

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:40', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e542beb7-1dc0-4d79-9fd2-5b8b5dd8606d'	System	02 Sep 2020 23:05:43
User entered '02 Sep 2020 19:05'	System	02 Sep 2020 23:05:43

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 4'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:18:39', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa555bad-6155-4d9d-8a82-744fb8e46f4d'	System	04 Sep 2020 00:19:01
User entered 'None (1)'	System	04 Sep 2020 00:19:01

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:18:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa555bad-6155-4d9d-8a82-744fb8e46f4d'	System	04 Sep 2020 00:19:01
User entered 'No (N)'	System	04 Sep 2020 00:19:01

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:18:47', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa555bad-6155-4d9d-8a82-744fb8e46f4d'	System	04 Sep 2020 00:19:01
User entered 'No (N)'	System	04 Sep 2020 00:19:01

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:18:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa555bad-6155-4d9d-8a82-744fb8e46f4d'	System	04 Sep 2020 00:19:01
User entered 'None (1)'	System	04 Sep 2020 00:19:01

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:18:58', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa555bad-6155-4d9d-8a82-744fb8e46f4d'	System	04 Sep 2020 00:19:01
User entered '03 Sep 2020 20:18'	System	04 Sep 2020 00:19:01

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 5'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:10', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'c691891e-a508-411d-a094-6b67665f03ad'	System	04 Sep 2020 21:58:35
User entered 'None (1)'	System	04 Sep 2020 21:58:35

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:16', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'c691891e-a508-411d-a094-6b67665f03ad'	System	04 Sep 2020 21:58:35
User entered 'No (N)'	System	04 Sep 2020 21:58:35

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:20', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'c691891e-a508-411d-a094-6b67665f03ad'	System	04 Sep 2020 21:58:35
User entered 'No (N)'	System	04 Sep 2020 21:58:35

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:28', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'c691891e-a508-411d-a094-6b67665f03ad'	System	04 Sep 2020 21:58:35
User entered 'None (1)'	System	04 Sep 2020 21:58:35

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:31', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'c691891e-a508-411d-a094-6b67665f03ad'	System	04 Sep 2020 21:58:35
User entered '04 Sep 2020 17:58'	System	04 Sep 2020 21:58:35

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 6'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:52:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e010fe32-ce36-4e2b-b510-23d2127e902c'	System	05 Sep 2020 21:53:03
User entered 'None (1)'	System	05 Sep 2020 21:53:03

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:52:49', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e010fe32-ce36-4e2b-b510-23d2127e902c'	System	05 Sep 2020 21:53:03
User entered 'No (N)'	System	05 Sep 2020 21:53:03

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:52:53', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e010fe32-ce36-4e2b-b510-23d2127e902c'	System	05 Sep 2020 21:53:03
User entered 'No (N)'	System	05 Sep 2020 21:53:03

FDA-CBER-2022-1614-1737044

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:52:58', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e010fe32-ce36-4e2b-b510-23d2127e902c'	System	05 Sep 2020 21:53:03
User entered 'None (1)'	System	05 Sep 2020 21:53:03

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e010fe32-ce36-4e2b-b510-23d2127e902c'	System	05 Sep 2020 21:53:03
User entered '05 Sep 2020 17:53'	System	05 Sep 2020 21:53:03

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:33:31
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 7'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:51:56', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd21b42ac-8f37-4fc9-a623-311963543c0c'	System	06 Sep 2020 20:52:20
User entered 'None (1)'	System	06 Sep 2020 20:52:20

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd21b42ac-8f37-4fc9-a623-311963543c0c'	System	06 Sep 2020 20:52:20
User entered 'No (N)'	System	06 Sep 2020 20:52:20

FDA-CBER-2022-1614-1737051

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:10', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd21b42ac-8f37-4fc9-a623-311963543c0c'	System	06 Sep 2020 20:52:20
User entered 'No (N)'	System	06 Sep 2020 20:52:20

US3402196

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:14', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd21b42ac-8f37-4fc9-a623-311963543c0c'	System	06 Sep 2020 20:52:20
User entered 'None (1)'	System	06 Sep 2020 20:52:20

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:18', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'd21b42ac-8f37-4fc9-a623-311963543c0c'	System	06 Sep 2020 20:52:20
User entered '06 Sep 2020 16:52'	System	06 Sep 2020 20:52:20

US3402196
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:57:56', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3a39f3db-0e3e-427f-906b-3704175202fd'	System	31 Aug 2020 12:58:36
User entered 'None (0)'	System	31 Aug 2020 12:58:36

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:58:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3a39f3db-0e3e-427f-906b-3704175202fd'	System	31 Aug 2020 12:58:36
User entered 'None (0)'	System	31 Aug 2020 12:58:36

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:58:07', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3a39f3db-0e3e-427f-906b-3704175202fd'	System	31 Aug 2020 12:58:36
User entered 'None (0)'	System	31 Aug 2020 12:58:36

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:58:11', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3a39f3db-0e3e-427f-906b-3704175202fd'	System	31 Aug 2020 12:58:36
User entered 'None (0)'	System	31 Aug 2020 12:58:36

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:58:16', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3a39f3db-0e3e-427f-906b-3704175202fd'	System	31 Aug 2020 12:58:36
User entered 'None (0)'	System	31 Aug 2020 12:58:36

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:58:20', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3a39f3db-0e3e-427f-906b-3704175202fd'	System	31 Aug 2020 12:58:36
User entered 'None (0)'	System	31 Aug 2020 12:58:36

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:58:26', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3a39f3db-0e3e-427f-906b-3704175202fd'	System	31 Aug 2020 12:58:36
User entered 'No (N)'	System	31 Aug 2020 12:58:36

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T08:58:30', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3a39f3db-0e3e-427f-906b-3704175202fd'	System	31 Aug 2020 12:58:36
User entered '31 Aug 2020 08:58'	System	31 Aug 2020 12:58:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 08:28'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 10:58'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:04:56', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '75129142-cd5b-4c68-82f6-e07ea7c84f2d'	System	31 Aug 2020 23:05:30
User entered 'None (0)'	System	31 Aug 2020 23:05:30

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:05:02', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '75129142-cd5b-4c68-82f6-e07ea7c84f2d'	System	31 Aug 2020 23:05:30
User entered 'None (0)'	System	31 Aug 2020 23:05:30

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:05:07', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '75129142-cd5b-4c68-82f6-e07ea7c84f2d'	System	31 Aug 2020 23:05:30
User entered 'None (0)'	System	31 Aug 2020 23:05:30

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:05:11', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '75129142-cd5b-4c68-82f6-e07ea7c84f2d'	System	31 Aug 2020 23:05:30
User entered 'None (0)'	System	31 Aug 2020 23:05:30

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:05:15', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '75129142-cd5b-4c68-82f6-e07ea7c84f2d'	System	31 Aug 2020 23:05:30
User entered 'None (0)'	System	31 Aug 2020 23:05:30

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:05:20', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '75129142-cd5b-4c68-82f6-e07ea7c84f2d'	System	31 Aug 2020 23:05:30
User entered 'None (0)'	System	31 Aug 2020 23:05:30

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:05:25', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '75129142-cd5b-4c68-82f6-e07ea7c84f2d'	System	31 Aug 2020 23:05:30
User entered 'No (N)'	System	31 Aug 2020 23:05:30

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:33:31
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-08-31T19:05:28', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '75129142-cd5b-4c68-82f6-e07ea7c84f2d'	System	31 Aug 2020 23:05:30
User entered '31 Aug 2020 19:05'	System	31 Aug 2020 23:05:30

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '31 Aug 2020 11:53'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 2'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:20', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '55db3d17-094e-46bd-babc-2d3fc6d0f9e7'	System	01 Sep 2020 20:57:00
User entered 'None (0)'	System	01 Sep 2020 20:57:00

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:24', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '55db3d17-094e-46bd-babc-2d3fc6d0f9e7'	System	01 Sep 2020 20:57:00
User entered 'None (0)'	System	01 Sep 2020 20:57:00

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:30', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '55db3d17-094e-46bd-babc-2d3fc6d0f9e7'	System	01 Sep 2020 20:57:00
User entered 'None (0)'	System	01 Sep 2020 20:57:00

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:35', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '55db3d17-094e-46bd-babc-2d3fc6d0f9e7'	System	01 Sep 2020 20:57:00
User entered 'None (0)'	System	01 Sep 2020 20:57:00

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '55db3d17-094e-46bd-babc-2d3fc6d0f9e7'	System	01 Sep 2020 20:57:00
User entered 'None (0)'	System	01 Sep 2020 20:57:00

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:48', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '55db3d17-094e-46bd-babc-2d3fc6d0f9e7'	System	01 Sep 2020 20:57:00
User entered 'None (0)'	System	01 Sep 2020 20:57:00

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:53', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '55db3d17-094e-46bd-babc-2d3fc6d0f9e7'	System	01 Sep 2020 20:57:00
User entered 'No (N)'	System	01 Sep 2020 20:57:00

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-01T16:56:57', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '55db3d17-094e-46bd-babc-2d3fc6d0f9e7'	System	01 Sep 2020 20:57:00
User entered '01 Sep 2020 16:56'	System	01 Sep 2020 20:57:00

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 3'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:48', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dddbe71-4803-4cb9-a98a-ff9efd3aea26'	System	02 Sep 2020 23:06:18
User entered 'None (0)'	System	02 Sep 2020 23:06:18

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:51', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dddbe71-4803-4cb9-a98a-ff9efd3aea26'	System	02 Sep 2020 23:06:18
User entered 'None (0)'	System	02 Sep 2020 23:06:18

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:05:58', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dddbe71-4803-4cb9-a98a-ff9efd3aea26'	System	02 Sep 2020 23:06:18
User entered 'None (0)'	System	02 Sep 2020 23:06:18

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:06:02', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dddbe71-4803-4cb9-a98a-ff9efd3aea26'	System	02 Sep 2020 23:06:18
User entered 'None (0)'	System	02 Sep 2020 23:06:18

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:06:06', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dddbe71-4803-4cb9-a98a-ff9efd3aea26'	System	02 Sep 2020 23:06:18
User entered 'None (0)'	System	02 Sep 2020 23:06:18

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:06:10', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dddbe71-4803-4cb9-a98a-ff9efd3aea26'	System	02 Sep 2020 23:06:18
User entered 'None (0)'	System	02 Sep 2020 23:06:18

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:06:14', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dddbe71-4803-4cb9-a98a-ff9efd3aea26'	System	02 Sep 2020 23:06:18
User entered 'No (N)'	System	02 Sep 2020 23:06:18

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-02T19:06:17', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6dddbe71-4803-4cb9-a98a-ff9efd3aea26'	System	02 Sep 2020 23:06:18
User entered '02 Sep 2020 19:06'	System	02 Sep 2020 23:06:18

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 4'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:19:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2d2da29-f283-48cc-9c86-7918795c4387'	System	04 Sep 2020 00:19:37
User entered 'None (0)'	System	04 Sep 2020 00:19:37

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:19:08', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2d2da29-f283-48cc-9c86-7918795c4387'	System	04 Sep 2020 00:19:37
User entered 'None (0)'	System	04 Sep 2020 00:19:37

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:19:11', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2d2da29-f283-48cc-9c86-7918795c4387'	System	04 Sep 2020 00:19:37
User entered 'None (0)'	System	04 Sep 2020 00:19:37

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:19:15', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2d2da29-f283-48cc-9c86-7918795c4387'	System	04 Sep 2020 00:19:37
User entered 'None (0)'	System	04 Sep 2020 00:19:37

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:19:19', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2d2da29-f283-48cc-9c86-7918795c4387'	System	04 Sep 2020 00:19:37
User entered 'None (0)'	System	04 Sep 2020 00:19:37

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:19:22', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2d2da29-f283-48cc-9c86-7918795c4387'	System	04 Sep 2020 00:19:37
User entered 'None (0)'	System	04 Sep 2020 00:19:37

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:19:28', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2d2da29-f283-48cc-9c86-7918795c4387'	System	04 Sep 2020 00:19:37
User entered 'No (N)'	System	04 Sep 2020 00:19:37

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-03T20:19:32', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'e2d2da29-f283-48cc-9c86-7918795c4387'	System	04 Sep 2020 00:19:37
User entered '03 Sep 2020 20:19'	System	04 Sep 2020 00:19:37

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 5'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:36', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '35e05980-4e24-4f18-990c-29e60df103c1'	System	04 Sep 2020 21:59:07
User entered 'None (0)'	System	04 Sep 2020 21:59:07

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:41', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '35e05980-4e24-4f18-990c-29e60df103c1'	System	04 Sep 2020 21:59:07
User entered 'None (0)'	System	04 Sep 2020 21:59:07

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:46', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '35e05980-4e24-4f18-990c-29e60df103c1'	System	04 Sep 2020 21:59:07
User entered 'None (0)'	System	04 Sep 2020 21:59:07

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:49', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '35e05980-4e24-4f18-990c-29e60df103c1'	System	04 Sep 2020 21:59:07
User entered 'None (0)'	System	04 Sep 2020 21:59:07

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:53', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '35e05980-4e24-4f18-990c-29e60df103c1'	System	04 Sep 2020 21:59:07
User entered 'None (0)'	System	04 Sep 2020 21:59:07

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:58:56', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '35e05980-4e24-4f18-990c-29e60df103c1'	System	04 Sep 2020 21:59:07
User entered 'None (0)'	System	04 Sep 2020 21:59:07

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:59:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '35e05980-4e24-4f18-990c-29e60df103c1'	System	04 Sep 2020 21:59:07
User entered 'No (N)'	System	04 Sep 2020 21:59:07

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US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-04T17:59:04', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '35e05980-4e24-4f18-990c-29e60df103c1'	System	04 Sep 2020 21:59:07
User entered '04 Sep 2020 17:59'	System	04 Sep 2020 21:59:07

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 6'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:09', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8271d6bc-ac43-4d9f-b49c-d2b3621efcb6'	System	05 Sep 2020 21:53:40
User entered 'None (0)'	System	05 Sep 2020 21:53:40

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:12', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8271d6bc-ac43-4d9f-b49c-d2b3621efcb6'	System	05 Sep 2020 21:53:40
User entered 'None (0)'	System	05 Sep 2020 21:53:40

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:16', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8271d6bc-ac43-4d9f-b49c-d2b3621efcb6'	System	05 Sep 2020 21:53:40
User entered 'None (0)'	System	05 Sep 2020 21:53:40

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:21', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8271d6bc-ac43-4d9f-b49c-d2b3621efcb6'	System	05 Sep 2020 21:53:40
User entered 'None (0)'	System	05 Sep 2020 21:53:40

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:25', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8271d6bc-ac43-4d9f-b49c-d2b3621efcb6'	System	05 Sep 2020 21:53:40
User entered 'None (0)'	System	05 Sep 2020 21:53:40

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:29', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8271d6bc-ac43-4d9f-b49c-d2b3621efcb6'	System	05 Sep 2020 21:53:40
User entered 'None (0)'	System	05 Sep 2020 21:53:40

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:33:31
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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:35', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8271d6bc-ac43-4d9f-b49c-d2b3621efcb6'	System	05 Sep 2020 21:53:40
User entered 'No (N)'	System	05 Sep 2020 21:53:40

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-05T17:53:38', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8271d6bc-ac43-4d9f-b49c-d2b3621efcb6'	System	05 Sep 2020 21:53:40
User entered '05 Sep 2020 17:53'	System	05 Sep 2020 21:53:40

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	31 Aug 2020 12:17:13
User entered 'Day 7'	System	31 Aug 2020 12:17:13

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:28', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'a327522c-a16f-4c37-929e-82806c256041'	System	06 Sep 2020 20:52:57
User entered 'None (0)'	System	06 Sep 2020 20:52:57

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:32', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'a327522c-a16f-4c37-929e-82806c256041'	System	06 Sep 2020 20:52:57
User entered 'None (0)'	System	06 Sep 2020 20:52:57

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:36', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'a327522c-a16f-4c37-929e-82806c256041'	System	06 Sep 2020 20:52:57
User entered 'None (0)'	System	06 Sep 2020 20:52:57

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:40', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'a327522c-a16f-4c37-929e-82806c256041'	System	06 Sep 2020 20:52:57
User entered 'None (0)'	System	06 Sep 2020 20:52:57

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:43', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'a327522c-a16f-4c37-929e-82806c256041'	System	06 Sep 2020 20:52:57
User entered 'None (0)'	System	06 Sep 2020 20:52:57

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:47', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'a327522c-a16f-4c37-929e-82806c256041'	System	06 Sep 2020 20:52:57
User entered 'None (0)'	System	06 Sep 2020 20:52:57

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:50', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'a327522c-a16f-4c37-929e-82806c256041'	System	06 Sep 2020 20:52:57
User entered 'No (N)'	System	06 Sep 2020 20:52:57

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-09-06T16:52:55', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'a327522c-a16f-4c37-929e-82806c256041'	System	06 Sep 2020 20:52:57
User entered '06 Sep 2020 16:52'	System	06 Sep 2020 20:52:57

US3402196
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:33:31
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 12:17:13

US3402196

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 12:17:13

US3402196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Sep 2020 20:01:28

US3402196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '8 Sep 2020'	Traci Hull (b) (4) (b) (4)	08 Sep 2020 20:01:28

Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	08 Sep 2020 20:01:28

US3402196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Sep 2020 20:01:28

US3402196

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Sep 2020 20:01:32

US3402196
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	08 Sep 2020 20:01:32

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 12:15:05

FDA-CBER-2022-1614-1737151

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 12:15:05

FDA-CBER-2022-1614-1737152

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 12:15:05

US3402196
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 12:15:05

US3402196

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 12:15:09

US3402196
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	14 Sep 2020 12:15:09

US3402196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 11:53:41

US3402196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '21 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 11:53:41

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 11:53:41

FDA-CBER-2022-1614-1737159

US3402196
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 11:53:41

US3402196

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 11:53:55

US3402196
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	22 Sep 2020 11:53:55

US3402196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	29 Sep 2020 12:30:53

US3402196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '29 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:30:53

US3402196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:30:53

US3402196
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User entered 'VISIT3'	System	29 Sep 2020 12:30:53

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '29 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '07:35'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User entered '29 Sep 2020 07:35'	System	29 Sep 2020 12:31:24

Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '98.2' F	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '71'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User entered 'bpm'	System	29 Sep 2020 12:31:24

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '14'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User entered 'breaths/min'	System	29 Sep 2020 12:31:24

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '163'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User entered 'mmHg'	System	29 Sep 2020 12:31:24

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '76'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:24

US3402196
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48
User entered 'mmHg'	System	29 Sep 2020 12:31:24

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48

US3402196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:48

US3402196

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:43

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered empty.	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:43

US3402196
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:33:31
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:55

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '29 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:55

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered '07:40'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '29 Sep 2020 07:40'	System	29 Sep 2020 12:31:55

FDA-CBER-2022-1614-1737189

US3402196

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 16:58:38
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 12:31:59

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	29 Sep 2020 12:31:59

FDA-CBER-2022-1614-1737191

US3402196
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 64'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-04T11:02:36', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '82224e6e-104d-4e1c-8cb0-1775065192b7'	System	04 Oct 2020 15:02:57
User entered 'No (N)'	System	04 Oct 2020 15:02:57

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-04T11:02:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '82224e6e-104d-4e1c-8cb0-1775065192b7'	System	04 Oct 2020 15:02:57
User entered 'No (N)'	System	04 Oct 2020 15:02:57

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-04T11:02:53', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '82224e6e-104d-4e1c-8cb0-1775065192b7'	System	04 Oct 2020 15:02:57
User entered '04 Oct 2020 11:02:53'	System	04 Oct 2020 15:02:57

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 71'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-11T10:57:03', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6fd8cf8c-5457-4884-846f-764e1e930698'	System	11 Oct 2020 14:57:22
User entered 'No (N)'	System	11 Oct 2020 14:57:22

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-11T10:57:14', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6fd8cf8c-5457-4884-846f-764e1e930698'	System	11 Oct 2020 14:57:22
User entered 'No (N)'	System	11 Oct 2020 14:57:22

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-11T10:57:21', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6fd8cf8c-5457-4884-846f-764e1e930698'	System	11 Oct 2020 14:57:22
User entered '11 Oct 2020 10:57:21'	System	11 Oct 2020 14:57:22

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 78'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-18T18:30:25', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6443ce86-ed90-4a8a-ae4f-061d55fbe6d3'	System	18 Oct 2020 22:30:43
User entered 'No (N)'	System	18 Oct 2020 22:30:43

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-18T18:30:34', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6443ce86-ed90-4a8a-ae4f-061d55fbe6d3'	System	18 Oct 2020 22:30:43
User entered 'No (N)'	System	18 Oct 2020 22:30:43

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-10-18T18:30:40', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '6443ce86-ed90-4a8a-ae4f-061d55fbe6d3'	System	18 Oct 2020 22:30:43
User entered '18 Oct 2020 18:30:40'	System	18 Oct 2020 22:30:43

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 92'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-03T10:03:07', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1684d69c-0b4a-46a4-82ba-2c5eb845cc35'	System	03 Nov 2020 15:03:23
User entered 'No (N)'	System	03 Nov 2020 15:03:23

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-03T10:03:14', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1684d69c-0b4a-46a4-82ba-2c5eb845cc35'	System	03 Nov 2020 15:03:23
User entered 'No (N)'	System	03 Nov 2020 15:03:23

US3402196
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-03T10:03:20', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1684d69c-0b4a-46a4-82ba-2c5eb845cc35'	System	03 Nov 2020 15:03:23
User entered '03 Nov 2020 10:03:20'	System	03 Nov 2020 15:03:23

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 99'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-08T18:48:25', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa90a67e-a303-4e27-8485-8154fadcc842'	System	08 Nov 2020 23:48:37
User entered 'No (N)'	System	08 Nov 2020 23:48:37

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-08T18:48:31', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa90a67e-a303-4e27-8485-8154fadcc842'	System	08 Nov 2020 23:48:37
User entered 'No (N)'	System	08 Nov 2020 23:48:37

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-08T18:48:36', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa90a67e-a303-4e27-8485-8154fadcc842'	System	08 Nov 2020 23:48:37
User entered '08 Nov 2020 18:48:36'	System	08 Nov 2020 23:48:37

FDA-CBER-2022-1614-1737219

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 12:51:17

US3402196
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered 'Day 106'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-15T07:29:29', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fc391459-1af2-486c-8115-edb1cfa14900'	System	15 Nov 2020 12:29:49
User entered 'No (N)'	System	15 Nov 2020 12:29:49

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-15T07:29:39', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fc391459-1af2-486c-8115-edb1cfa14900'	System	15 Nov 2020 12:29:49
User entered 'No (N)'	System	15 Nov 2020 12:29:49

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-15T07:29:45', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fc391459-1af2-486c-8115-edb1cfa14900'	System	15 Nov 2020 12:29:49
User entered '15 Nov 2020 07:29:45'	System	15 Nov 2020 12:29:49

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 12:51:17

US3402196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:05:11
Data entry locked.	System	03 Aug 2020 12:51:17
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 12:51:17

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-22T02:44:19', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1f24b80e-946c-43b6-bce7-6ddbbea1b298'	System	22 Nov 2020 07:44:34
User entered 'No (N)'	System	22 Nov 2020 07:44:34

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-22T02:44:27', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1f24b80e-946c-43b6-bce7-6ddbbea1b298'	System	22 Nov 2020 07:44:34
User entered 'No (N)'	System	22 Nov 2020 07:44:34

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-22T02:44:31', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1f24b80e-946c-43b6-bce7-6ddbbea1b298'	System	22 Nov 2020 07:44:34
User entered '22 Nov 2020 02:44:31'	System	22 Nov 2020 07:44:34

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-28T13:20:22', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa4f2ecd-74db-491c-8cbb-62d6dac43c4a'	System	28 Nov 2020 18:20:33
User entered 'No (N)'	System	28 Nov 2020 18:20:33

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-28T13:20:26', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa4f2ecd-74db-491c-8cbb-62d6dac43c4a'	System	28 Nov 2020 18:20:33
User entered 'No (N)'	System	28 Nov 2020 18:20:33

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-11-28T13:20:30', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'fa4f2ecd-74db-491c-8cbb-62d6dac43c4a'	System	28 Nov 2020 18:20:33
User entered '28 Nov 2020 13:20:30'	System	28 Nov 2020 18:20:33

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-06T08:47:34', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '00c70a37-d99e-47d9-a2dc-1ac13f0d5ddd'	System	06 Dec 2020 13:47:49
User entered 'No (N)'	System	06 Dec 2020 13:47:49

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-06T08:47:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '00c70a37-d99e-47d9-a2dc-1ac13f0d5ddd'	System	06 Dec 2020 13:47:49
User entered 'No (N)'	System	06 Dec 2020 13:47:49

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-06T08:47:49', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '00c70a37-d99e-47d9-a2dc-1ac13f0d5ddd'	System	06 Dec 2020 13:47:49
User entered '06 Dec 2020 08:47:49'	System	06 Dec 2020 13:47:49

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-17T09:30:59', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f9a71805-dcf6-482a-b89f-b552ea809991'	System	17 Dec 2020 14:31:58
User entered 'No (N)'	System	17 Dec 2020 14:31:58

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-17T09:31:23', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f9a71805-dcf6-482a-b89f-b552ea809991'	System	17 Dec 2020 14:31:58
User entered 'Yes (Y)'	System	17 Dec 2020 14:31:58

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-17T09:31:39', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f9a71805-dcf6-482a-b89f-b552ea809991'	System	17 Dec 2020 14:31:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 14:31:58

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-17T09:31:47', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f9a71805-dcf6-482a-b89f-b552ea809991'	System	17 Dec 2020 14:31:58
User entered '17 Dec 2020 09:31:47'	System	17 Dec 2020 14:31:58

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:45:38', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered 'Yes (Y)'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:45:47', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered 'Yes (Y)'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:45:58', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:46:16', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered 'Yes (Y)'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '1'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '1'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '1'	System	26 Dec 2020 03:47:43

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

Shortness of breath

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '1'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Difficulty breathing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '1'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Muscle aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Body aches

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '1'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
New loss of taste

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

New loss of smell

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Sore throat

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Congestion

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Runny nose

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '1'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '0'	System	26 Dec 2020 03:47:43

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '1'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:08', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:23', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered 'No (N)'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2020-12-25T22:47:30', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '8d2e5ae6-5daa-4256-9b7a-d1de0f92d643'	System	26 Dec 2020 03:47:43
User entered '25 Dec 2020 22:47:30'	System	26 Dec 2020 03:47:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-01-16T06:38:53', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '7fafc97e-fdd8-4456-8291-4c04167520d1'	System	27 Jan 2021 01:19:24
User entered 'No (N)'	System	27 Jan 2021 01:19:24

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-01-16T06:38:51', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '7fafc97e-fdd8-4456-8291-4c04167520d1'	System	27 Jan 2021 01:19:24
User entered 'Yes (Y)'	System	27 Jan 2021 01:19:24

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-01-16T06:38:50', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '7fafc97e-fdd8-4456-8291-4c04167520d1'	System	27 Jan 2021 01:19:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Jan 2021 01:19:24

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-01-16T06:39:15', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '7fafc97e-fdd8-4456-8291-4c04167520d1'	System	27 Jan 2021 01:19:24
User entered '16 Jan 2021 06:39:15'	System	27 Jan 2021 01:19:24

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-01-28T09:38:53', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '64d23342-ddb7-4d63-86e9-36ae6f24c292'	System	28 Jan 2021 14:39:13
User entered 'No (N)'	System	28 Jan 2021 14:39:13

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-01-28T09:39:01', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '64d23342-ddb7-4d63-86e9-36ae6f24c292'	System	28 Jan 2021 14:39:13
User entered 'No (N)'	System	28 Jan 2021 14:39:13

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-01-28T09:39:08', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '64d23342-ddb7-4d63-86e9-36ae6f24c292'	System	28 Jan 2021 14:39:13
User entered '28 Jan 2021 09:39:08'	System	28 Jan 2021 14:39:13

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-04T07:30:51', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '83f6b7fa-6f82-4d9f-8e31-a87c0d5aa505'	System	04 Feb 2021 12:31:06
User entered 'No (N)'	System	04 Feb 2021 12:31:06

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-04T07:30:55', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '83f6b7fa-6f82-4d9f-8e31-a87c0d5aa505'	System	04 Feb 2021 12:31:06
User entered 'No (N)'	System	04 Feb 2021 12:31:06

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-04T07:31:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '83f6b7fa-6f82-4d9f-8e31-a87c0d5aa505'	System	04 Feb 2021 12:31:06
User entered '04 Feb 2021 07:31:00'	System	04 Feb 2021 12:31:06

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-11T15:25:44', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3ba1243a-cff8-4815-ac74-634049d952fd'	System	11 Feb 2021 20:25:56
User entered 'No (N)'	System	11 Feb 2021 20:25:56

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-11T15:25:49', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3ba1243a-cff8-4815-ac74-634049d952fd'	System	11 Feb 2021 20:25:56
User entered 'No (N)'	System	11 Feb 2021 20:25:56

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-11T15:25:52', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3ba1243a-cff8-4815-ac74-634049d952fd'	System	11 Feb 2021 20:25:56
User entered '11 Feb 2021 15:25:52'	System	11 Feb 2021 20:25:56

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 11:36:07

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 11:36:07

FDA-CBER-2022-1614-1737319

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:36:07

FDA-CBER-2022-1614-1737320

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-27T16:16:30-05:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1bbf487e-838c-4c84-bc85-fd5715a3dd75'	System	27 Feb 2021 21:16:43
User entered 'No (N)'	System	27 Feb 2021 21:16:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-27T16:16:35-05:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1bbf487e-838c-4c84-bc85-fd5715a3dd75'	System	27 Feb 2021 21:16:43
User entered 'No (N)'	System	27 Feb 2021 21:16:43

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-02-27T16:16:42-05:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '1bbf487e-838c-4c84-bc85-fd5715a3dd75'	System	27 Feb 2021 21:16:43
User entered '27 Feb 2021 21:16:42'	System	27 Feb 2021 21:16:43

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-02T11:09:36-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '9e0f6a84-c1b4-4a6f-8468-0325b4a1908e'	System	02 Apr 2021 15:09:49
User entered 'No (N)'	System	02 Apr 2021 15:09:49

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-02T11:09:40-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '9e0f6a84-c1b4-4a6f-8468-0325b4a1908e'	System	02 Apr 2021 15:09:49
User entered 'No (N)'	System	02 Apr 2021 15:09:49

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-02T11:09:47-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '9e0f6a84-c1b4-4a6f-8468-0325b4a1908e'	System	02 Apr 2021 15:09:49
User entered '02 Apr 2021 15:09:47'	System	02 Apr 2021 15:09:49

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-08T10:59:05-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ee321ef0-c9f7-4b95-8a4f-33faac609a05'	System	08 Apr 2021 14:59:25
User entered 'No (N)'	System	08 Apr 2021 14:59:25

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-08T10:59:14-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ee321ef0-c9f7-4b95-8a4f-33faac609a05'	System	08 Apr 2021 14:59:25
User entered 'No (N)'	System	08 Apr 2021 14:59:25

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-08T10:59:20-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'ee321ef0-c9f7-4b95-8a4f-33faac609a05'	System	08 Apr 2021 14:59:25
User entered '08 Apr 2021 14:59:20'	System	08 Apr 2021 14:59:25

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-15T15:48:40-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3035f629-1422-4046-af9f-7d8104922599'	System	15 Apr 2021 19:48:57
User entered 'No (N)'	System	15 Apr 2021 19:48:57

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-15T15:48:46-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3035f629-1422-4046-af9f-7d8104922599'	System	15 Apr 2021 19:48:57
User entered 'No (N)'	System	15 Apr 2021 19:48:57

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-15T15:48:51-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: '3035f629-1422-4046-af9f-7d8104922599'	System	15 Apr 2021 19:48:57
User entered '15 Apr 2021 15:48:51'	System	15 Apr 2021 19:48:57

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 11:36:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-22T18:13:33-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bf6f50fc-e5fa-45fd-9e1c-98196adc1337'	System	22 Apr 2021 22:13:47
User entered 'No (N)'	System	22 Apr 2021 22:13:47

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-22T18:13:40-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bf6f50fc-e5fa-45fd-9e1c-98196adc1337'	System	22 Apr 2021 22:13:47
User entered 'No (N)'	System	22 Apr 2021 22:13:47

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-22T18:13:43-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bf6f50fc-e5fa-45fd-9e1c-98196adc1337'	System	22 Apr 2021 22:13:47
User entered '22 Apr 2021 18:13:43'	System	22 Apr 2021 22:13:47

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-30T11:22:59-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd424b3a-c456-4050-95c9-61fc16760409'	System	30 Apr 2021 15:23:11
User entered 'No (N)'	System	30 Apr 2021 15:23:11

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-30T11:23:04-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd424b3a-c456-4050-95c9-61fc16760409'	System	30 Apr 2021 15:23:11
User entered 'No (N)'	System	30 Apr 2021 15:23:11

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-30T11:23:09-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'bd424b3a-c456-4050-95c9-61fc16760409'	System	30 Apr 2021 15:23:11
User entered '30 Apr 2021 11:23:09'	System	30 Apr 2021 15:23:11

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:36:07

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US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 11:36:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 11:36:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:36:07

FDA-CBER-2022-1614-1737395

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:36:07

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 11:36:07

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:36:07

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US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 11:36:07

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:36:07

FDA-CBER-2022-1614-1737455

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 11:36:07

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 11:36:07

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:36:07

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US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:36:07

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US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 11:36:07

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 11:36:07

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:36:07

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US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:36:07

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 11:36:07

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 11:36:07

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 11:36:07

FDA-CBER-2022-1614-1737580

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:33:31
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 11:36:07

US3402196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:36:07
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 11:36:07

US3402196

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:33:31

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)	30 Apr 2021 16:33:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-22T18:14:00-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f4ff8da4-00d8-409e-bac0-6f46f16c0008'	System	22 Apr 2021 22:14:07
User entered 'No (N)'	System	22 Apr 2021 22:14:07

US3402196

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:33:31

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:33:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (936B6F70-1317-47BA-967B-5367F4773629)', Time: '2021-04-22T18:14:03-04:00', User OID: 'PatientReportedOutcome (US3402196)', ODM File OID: 'f4ff8da4-00d8-409e-bac0-6f46f16c0008'	System	22 Apr 2021 22:14:07
User entered '22 Apr 2021 18:14:03'	System	22 Apr 2021 22:14:07

US3402196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:19:44
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:46:08

US3402196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:19:44
User entered '26 Oct 2020'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:46:08

US3402196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:19:44
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:46:08

US3402196
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:19:44
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:46:08

US3402196

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:19:44
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 17:45:54

US3402196
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:42:43
User entered '1'	System	26 Oct 2020 17:45:54

US3402196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 17:00:26

US3402196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '27 Nov 2020'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 17:00:26

US3402196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 17:00:26

US3402196
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Nov 2020 17:00:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Nov 2020 17:00:10

US3402196
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User entered '1'	System	27 Nov 2020 17:00:10

US3402196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Dec 2020 20:33:18

US3402196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '28 Dec 2020'	Traci Hull (b) (4) (b) (4)	28 Dec 2020 20:33:18

US3402196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	28 Dec 2020 20:33:18

US3402196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Dec 2020 20:33:18

US3402196

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Dec 2020 20:33:24

US3402196

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User entered '1'	System	28 Dec 2020 20:33:24

US3402196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:03:09

US3402196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '25 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:03:09

US3402196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:03:09

US3402196
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:03:09

US3402196

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:03:13

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:21
User entered '1'	System	25 Jan 2021 21:03:13

US3402196
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User closed query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 23 Feb 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:24:23
Query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 23 Feb 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:00:49
User opened query 'Per CDM: Thank you for record the VS form. However, the response for Were vital signs assessed? is No. Visit 4 Day 209 and Visit OL-D29 are both dated 23 Feb 2021. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor with the same response Yes or No. Please review Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:44:21
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 23 Feb 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:44:21

US3402196
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was this visit performed?

Audit	User	Time (GMT)
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 23 Feb 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' answered with 'correct as is' (Site from DM).	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:42:02
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D29 are both dated 23 Feb 2021, however, Were vital signs assessed?' is not completed at this visit but at OL-D29 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the Assessment data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:09:26
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:38:10

US3402196
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '23 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:38:10

US3402196

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:38:10

US3402196
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User entered 'VISIT4'	System	23 Feb 2021 15:38:10

US3402196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

US3402196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '23 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

US3402196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '09:06' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User entered '23 Feb 2021 09:06'	System	01 Apr 2021 12:04:39
User entered empty.	System	30 Mar 2021 18:41:48

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '36.6' C reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Oral (Oral)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '64' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User entered 'bpm'	System	01 Apr 2021 12:04:39
User entered empty.	System	30 Mar 2021 18:41:48

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '18' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User entered 'breaths/min'	System	01 Apr 2021 12:04:39
User entered empty.	System	30 Mar 2021 18:41:48

FDA-CBER-2022-1614-1737634

US3402196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '136' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User entered 'mmHg'	System	01 Apr 2021 12:04:39
User entered empty.	System	30 Mar 2021 18:41:48

US3402196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '78' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 12:04:39
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 18:41:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User entered 'mmHg'	System	01 Apr 2021 12:04:39
User entered empty.	System	30 Mar 2021 18:41:48

FDA-CBER-2022-1614-1737638

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54

US3402196
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:38:15

US3402196

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:38:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Mar 2021 13:51:21

FDA-CBER-2022-1614-1737643

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '23 Feb 2021'	Traci Hull (b) (4) (b) (4)	03 Mar 2021 13:51:21

FDA-CBER-2022-1614-1737644

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '09:20'	Traci Hull (b) (4) (b) (4)	03 Mar 2021 13:51:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User entered '23 Feb 2021 09:20'	System	03 Mar 2021 13:51:21

US3402196
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:38:17

US3402196

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:54
User entered '1'	System	23 Feb 2021 15:38:17

US3402196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:59:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:31:47

US3402196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:59:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:31:47

FDA-CBER-2022-1614-1737650

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:59:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:31:47

US3402196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:59:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:31:47

US3402196

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:59:44
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:31:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:59:44
User entered '1'	System	26 Mar 2021 13:31:53

FDA-CBER-2022-1614-1737654

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:33:31
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 16:41:55
User entered '29 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:51:29

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:33:31

Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:41:55
User entered '07:30'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:51:29

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:33:31
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:53
User entered '29 Dec 2020 07:30'	System	29 Dec 2020 13:51:29

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:33:31
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:41:55
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:51:29

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:33:31

Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:24:53
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:41:55
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:51:29

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 1 (Day 1)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '17 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:52:34
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:52:34

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 2 (Day 2)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '18 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:33:31
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:53:06

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:53:06
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:53:06
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:06

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '19 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:53:34

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:53:34
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:53:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 4 (Day 4)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '20 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4)	29 Dec 2020 13:54:09
	(b) (4)	

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:54:09

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US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:54:09

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '21 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:33:31
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:55:13
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:55:13

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 6 (Day 6)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '22 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:56:46

FDA-CBER-2022-1614-1737774

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

FDA-CBER-2022-1614-1737776

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:56:46
	(b) (4)	

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:33:31
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

FDA-CBER-2022-1614-1737789

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

FDA-CBER-2022-1614-1737790

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '23 Dec 2020'	Traci Hull (b) (4)	29 Dec 2020 13:57:31
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

FDA-CBER-2022-1614-1737799

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:57:31
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:57:31
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:57:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 8 (Day 8)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '24 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4)	29 Dec 2020 13:58:52
	(b) (4)	

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:58:52
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:58:52
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:58:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '25 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:59:19
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:19

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 10 (Day 10)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '26 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 13:59:43
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 13:59:43

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 11 (Day 11)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '27 Dec 2020'	Traci Hull (b) (4)	29 Dec 2020 14:00:16
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 14:00:16

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 14:00:16
	(b) (4)	

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 14:00:16
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:16

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 12 (Day 12)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

FDA-CBER-2022-1614-1737902

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '28 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 14:00:53

FDA-CBER-2022-1614-1737906

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 14:00:53
	(b) (4)	

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:00:53

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 13 (Day 13)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '29 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:33:31
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '99'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '36.3' C	Traci Hull (b) (4)	29 Dec 2020 14:01:56
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 14:01:56
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	29 Dec 2020 14:01:56
	(b) (4)	

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:01:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '30 Dec 2020'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4)	06 Jan 2021 17:47:07
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '93'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '99.6' F	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:47:07

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 15 (Day 15)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '31 Dec 2020'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '94'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	06 Jan 2021 17:50:20

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '99.2' F	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:20

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 16 (Day 16)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

FDA-CBER-2022-1614-1737990

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '01 Jan 2021'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '93'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	06 Jan 2021 17:50:59

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '98.8' F	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	06 Jan 2021 17:50:59
	(b) (4)	

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

FDA-CBER-2022-1614-1738003

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	06 Jan 2021 17:50:59
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:50:59

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Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 17 (Day 17)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '2 Jan 2021'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '93'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '98.4' F	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:52:52

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 18 (Day 18)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '03 Jan 2021'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '94'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	06 Jan 2021 17:53:29

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Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '98.7' F	Traci Hull (b) (4)	06 Jan 2021 17:53:29
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4)	06 Jan 2021 17:53:29
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	06 Jan 2021 17:53:29
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:53:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	06 Jan 2021 17:53:29
	(b) (4)	

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Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 19 (Day 19)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '04 Jan 2021'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.2' F	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	06 Jan 2021 17:54:04
	(b) (4)	

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Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4)	06 Jan 2021 17:54:04
	(b) (4)	

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Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:04

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 20 (Day 20)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '05 Jan 2021'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '95'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '98.0' F	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	06 Jan 2021 17:54:41
	(b) (4)	

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Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:54:41

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Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '06 Jan 2021'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '99'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.6' F	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	07 Jan 2021 13:10:17
	(b) (4)	

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:33:31
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:17

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 22 (Day 22)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '07 Jan 2021'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '98'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	08 Jan 2021 15:44:29

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:33:31
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	08 Jan 2021 15:44:29

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Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 23 (Day 23)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '08 Jan 2021'	Traci Hull (b) (4)	11 Jan 2021 14:34:08
	(b) (4)	

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Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '98'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	11 Jan 2021 14:34:08

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Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.5' F	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:08

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Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 24 (Day 24)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

FDA-CBER-2022-1614-1738166

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '09 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

FDA-CBER-2022-1614-1738169

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.8' F	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	11 Jan 2021 14:34:47
	(b) (4)	

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New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	11 Jan 2021 14:34:47
	(b) (4)	

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:34:47

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:33:31
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 25 (Day 25)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '10 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '98.4' F	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:33:31
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4)	11 Jan 2021 14:35:21
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:33:31
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 14:35:21

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 26 (Day 26)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

FDA-CBER-2022-1614-1738210

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	18 Jan 2021 12:37:55

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Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.5' F	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	18 Jan 2021 12:37:55
	(b) (4)	

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Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	18 Jan 2021 12:37:55
	(b) (4)	

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Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (31)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:37:55

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 27 (Day 27)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '12 Jan 2021'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	18 Jan 2021 12:39:05
	(b) (4)	

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

FDA-CBER-2022-1614-1738244

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Form: Symptom Log (32)

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New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

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Form: Symptom Log (32)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:05

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '13 Jan 2021'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:33:31
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	18 Jan 2021 12:39:56
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (33)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:33:31
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:39:56

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (34)
Generated On: 11 Aug 2021 22:33:31
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 29 (Day 29)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (34)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '14 Jan 2021'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.8' F	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (34)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Form: Symptom Log (34)

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Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	18 Jan 2021 12:40:29
	(b) (4)	

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (34)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (34)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (34)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:40:29

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 30 (Day 30)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (35)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '15 Jan 2021'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (35)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (35)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	18 Jan 2021 12:41:38
	(b) (4)	

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (35)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (35)
Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (35)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	18 Jan 2021 12:41:38

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 31 (Day 31)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '16 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96.8' F	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (36)
Generated On: 11 Aug 2021 22:33:31
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (36)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

FDA-CBER-2022-1614-1738335

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	20 Jan 2021 14:25:11
	(b) (4)	

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (36)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

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Form: Symptom Log (36)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:11

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 32 (Day 32)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '17 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (37)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (37)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (37)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (37)
Generated On: 11 Aug 2021 22:33:31
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (37)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (37)
Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (37)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (37)
Generated On: 11 Aug 2021 22:33:31
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Form: Symptom Log (37)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:25:54

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Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 33 (Day 33)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (38)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '18 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	20 Jan 2021 14:26:39

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (38)
Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.2' F	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (38)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	20 Jan 2021 14:26:39
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (38)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4)	20 Jan 2021 14:26:39
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (38)
Generated On: 11 Aug 2021 22:33:31
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (38)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Form: Symptom Log (38)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:26:39

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (39)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 34 (Day 34)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Folder: Covid-19 Assessment 29 Dec 2020
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Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	20 Jan 2021 14:27:01

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (39)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Jan 2021 14:28:52
User entered '97.3' F reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Jan 2021 14:27:01
User entered '97' (non-conformant).	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	20 Jan 2021 14:28:52
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Form: Symptom Log (39)
Generated On: 11 Aug 2021 22:33:31
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (39)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	20 Jan 2021 14:28:52
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	20 Jan 2021 14:27:01
	(b) (4)	

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Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Form: Symptom Log (39)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Form: Symptom Log (39)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Form: Symptom Log (39)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Form: Symptom Log (39)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Form: Symptom Log (39)

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Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

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Form: Symptom Log (39)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:28:52
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:27:01

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 35 (Day 35)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (40)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '20 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	21 Jan 2021 17:50:03

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Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Form: Symptom Log (40)
Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Form: Symptom Log (40)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Form: Symptom Log (40)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Form: Symptom Log (40)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (40)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Form: Symptom Log (40)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Form: Symptom Log (40)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Form: Symptom Log (40)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Form: Symptom Log (40)

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Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 17:50:03

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Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 36 (Day 36)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (41)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '21 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	25 Jan 2021 21:48:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.3' F	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (41)
Generated On: 11 Aug 2021 22:33:31
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (41)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (41)
Generated On: 11 Aug 2021 22:33:31
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (41)
Generated On: 11 Aug 2021 22:33:31
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (41)
Generated On: 11 Aug 2021 22:33:31
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Form: Symptom Log (41)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:48:20

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Form: Symptom Log (42)
Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 37 (Day 37)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '22 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (42)
Generated On: 11 Aug 2021 22:33:31
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '96'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (42)
Generated On: 11 Aug 2021 22:33:31
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.6' F	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (42)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (42)
Generated On: 11 Aug 2021 22:33:31
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Form: Symptom Log (42)
Generated On: 11 Aug 2021 22:33:31
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4)	25 Jan 2021 21:52:00
	(b) (4)	

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Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (42)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:52:00

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 38 (Day 38)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '23 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	25 Jan 2021 21:53:23

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.8' F	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (43)
Generated On: 11 Aug 2021 22:33:31
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (43)
Generated On: 11 Aug 2021 22:33:31

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (43)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:53:23

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Day 39 (Day 39)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (44)
Generated On: 11 Aug 2021 22:33:31
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '24 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '0'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User entered '%'	System	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered '97.2' F	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (44)
Generated On: 11 Aug 2021 22:33:31
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:55:12
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (44)
Generated On: 11 Aug 2021 22:33:31
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4)	25 Jan 2021 21:54:51
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Symptom Log (44)
Generated On: 11 Aug 2021 22:33:31
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Symptom Log (44)

Generated On: 11 Aug 2021 22:33:31

Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:02
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:06
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:54:51

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Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:05:37
User entered '29 Dec 2020'	Traci Hull (b) (4)	29 Dec 2020 14:02:34
	(b) (4)	

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Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:05:37
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:05:37
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)	12 Jan 2021 08:34:01
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 'Correct as is' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:55:41
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	05 Jan 2021 11:55:12
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:55:12
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:34

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:33:31
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:05:37
User entered '29 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:34

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:33:31

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:05:37
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:34

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:33:31
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:05:37
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:34

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Folder: Covid-19 Assessment 29 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

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)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:05:37
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:34

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:33:31
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:05:37
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:34

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Folder: Covid-19 Assessment 29 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:33:31

CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:05:37
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:34

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EAB) (1725)

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Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:11
User entered '1'	System	05 Jan 2021 11:55:12
User entered '0'	System	29 Dec 2020 14:02:34

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4)	05 Jan 2021 11:56:46
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

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)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:10:24
DataPoint Un-verified.	Jennifer Molstead (b) (4)	16 Feb 2021 20:58:37
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4) (b) (4)	16 Feb 2021 20:58:37
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:10:26
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	16 Feb 2021 20:58:37
User entered '30 Dec 2020' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	16 Feb 2021 20:58:37
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:10:27
DataPoint Un-verified.	Jennifer Molstead (b) (4)	16 Feb 2021 20:58:37
User entered '2 Jan 2021' reason for change: New Information	Jennifer Molstead (b) (4)	16 Feb 2021 20:58:37
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User closed query 'Per CDM: Value for oxygen saturation is missing. Kindly review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:29:02
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 22:11:49
Query 'Per CDM: Value for oxygen saturation is missing. Kindly review and update as appropriate. Thank you.' answered with 'UPDATED PER CHART O2 SATURATION 93%' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 17:14:58
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 17:14:26
User entered '93' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 17:14:26
User opened query 'Per CDM: Value for oxygen saturation is missing. Kindly review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 06:28:39
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

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Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020

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End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Generated On: 11 Aug 2021 22:33:31

Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Start Date

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

FDA-CBER-2022-1614-1738568

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196
Folder: Covid-19 Assessment 29 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:33:31
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4)	05 Jan 2021 11:56:46
	(b) (4)	

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:16
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:06:05
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:56:46

US3402196

Folder: Covid-19 Assessment 29 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:33:31

Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:25:21
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:06:23
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:15:12
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:02:41

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:33:31

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:33:31

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered '31 Dec 2020'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

FDA-CBER-2022-1614-1738582

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:33:31

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:33:31
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 5 Sample with collection date of " 02 JAN 2021" in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:12:11
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 5 Sample with collection date of " 02 JAN 2021" in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:52:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:52:07
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 5 Sample with collection date of " 02 JAN 2021" in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 17:47:53
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 22:11:44
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered '02 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:52:07
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please provide the accession number for reference.Thanks' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 08:19:38
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please provide the accession number for reference.Thanks' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:29:35
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 15:29:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please provide the accession number for reference.Thanks' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 05:31:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02JAN2021 is recorded under Illness visit 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)	22 Jan 2021 05:31:06
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02JAN2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Jan 2021 22:11:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02JAN2021 is recorded under Illness visit 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)	15 Jan 2021 09:03:21

PRODUCTION RELEASE (v12.003 EAB) (1725)

FDA-CBER-2022-1614-1738585

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01JAN2021 is recorded under Illness visit 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)	15 Jan 2021 09:03:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01JAN2021 is recorded under Illness visit 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)	15 Jan 2021 09:02:31
User entered '02 Jan 2021'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:33:31

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:33:31

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered '04 Jan 2021'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:33:31

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:33:31

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:44
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

FDA-CBER-2022-1614-1738591

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered '6 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	07 Jan 2021 13:10:44
User entered empty.	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:33:31

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:33:31

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:31:17
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:33:31
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 14 SALIVA sample is recorded as collected on 08" JAN 2021", however in EDC, it is recorded as collected on "11 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:12:23
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 14 SALIVA sample is recorded as collected on 08" JAN 2021", however in EDC, it is recorded as collected on "11 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' answered with 'DATA UPDATED TO CORRECT DATE 08 JAN 2021' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:53:36
User entered '08 Jan 2021' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:53:07
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 14 SALIVA sample is recorded as collected on 08" JAN 2021", however in EDC, it is recorded as collected on "11 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 17:49:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness Visit Day 14 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)	14 Feb 2021 17:48:18

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness Visit Day 14 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 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 13:33:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness Visit Day 14 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)	29 Jan 2021 05:09:05
User entered '11 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:31:17
User entered empty.	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:33:31

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:33:31

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 21 SALIVA sample is recorded as collected on "15 JAN 2021", however in EDC, it is recorded as collected on "18 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:12:33
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 21 SALIVA sample is recorded as collected on "15 JAN 2021", however in EDC, it is recorded as collected on "18 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' answered with 'UPDATED ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:54:10
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this DAY 21 SALIVA sample is recorded as collected on "15 JAN 2021", however in EDC, it is recorded as collected on "18 JAN 2021". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 17:51:00
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:31:17
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User entered '15 Jan 2021' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:54:04
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 21 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)	14 Feb 2021 17:50:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 21 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 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 13:33:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 21 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)	29 Jan 2021 05:09:15
User entered '18 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	20 Jan 2021 14:31:17
User entered empty.	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:33:31

Visit

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:33:31

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User closed query 'Per CDM: Was Saliva Collected? Is recorded as "No" However Date of Collection is recorded as 25JAN2021. Please review and update, else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:02:10
Query 'Per CDM: Was Saliva Collected? Is recorded as "No" However Date of Collection is recorded as 25JAN2021. Please review and update, else clarify. ' answered with 'DATE HAS BEEN REMOVED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	10 Feb 2021 16:17:46
User opened query 'Per CDM: Was Saliva Collected? Is recorded as "No" However Date of Collection is recorded as 25JAN2021. Please review and update, else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:28:19
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:36
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 28 Sample with collection date of 25 JAN 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:12:30
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 28 Sample with collection date of 25 JAN 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' answered with 'DATA CORRECTED TO 25 JAN 2021' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:54:43
User entered '25 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:54:32
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 28 Sample with collection date of 25 JAN 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 17:52:14
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	10 Feb 2021 16:17:32
User entered '25 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:45:56
User entered empty.	Traci Hull (b) (4) (b) (4)	06 Jan 2021 17:56:43

US3402196
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:10:19
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:01

US3402196
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:10:19
User entered '29 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:01

US3402196

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:10:19
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:01

US3402196
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'SICKD1'	System	29 Dec 2020 14:03:01

US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:44

US3402196

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered '29 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:44

US3402196

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered '07:30'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:44

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered '29 Dec 2020 07:30'	System	29 Dec 2020 14:03:44

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US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered missing code ND - Not Done.	Traci Hull (b) (4)	29 Dec 2020 14:03:44
DataPoint set to visible.	System	29 Dec 2020 14:03:01

US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered missing code ND - Not Done.	Traci Hull (b) (4)	29 Dec 2020 14:03:44
	(b) (4)	
DataPoint set to visible.	System	29 Dec 2020 14:03:01

US3402196

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered '36.3' C	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:44

US3402196

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:44

US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered empty.	Traci Hull (b) (4)	29 Dec 2020 14:03:44
	(b) (4)	

US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered '99'	Traci Hull (b) (4)	29 Dec 2020 14:03:44
	(b) (4)	

US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'bpm'	System	29 Dec 2020 14:03:44

US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered '15'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:44

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'breaths/min'	System	29 Dec 2020 14:03:44

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US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered '132'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:44

US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'mmHg'	System	29 Dec 2020 14:03:44

US3402196

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:16:42
User entered '80'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:44

US3402196
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User entered 'mmHg'	System	29 Dec 2020 14:03:44

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42

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US3402196

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42

US3402196

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:18:19
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:55

US3402196

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:18:19
User entered '29 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:03:55

Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:33:31
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:18:27
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:04:05

FDA-CBER-2022-1614-1738628

US3402196

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:18:27
User entered '29 Dec 2020'	Traci Hull (b) (4) (b) (4)	29 Dec 2020 14:04:05

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:22:17
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:43:48

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:22:17
User entered '25 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:43:48

US3402196

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:22:17
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:43:48

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'SICKD28'	System	25 Jan 2021 21:43:48

US3402196

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered '25 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered '14:46'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered '25 Jan 2021 14:46'	System	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered missing code ND - Not Done.	Tammy Kohn (b) (4)	25 Jan 2021 21:44:46
DataPoint set to visible.	(b) (4) System	25 Jan 2021 21:43:48

US3402196

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered '206' lb	Tammy Kohn (b) (4)	25 Jan 2021 21:44:46
DataPoint set to visible.	(b) (4) System	25 Jan 2021 21:43:48

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered '36.5' C	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered empty.	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered '89'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'bpm'	System	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered '16'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'breaths/min'	System	25 Jan 2021 21:44:46

US3402196

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered '142'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'mmHg'	System	25 Jan 2021 21:44:46

Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:24:20
User entered '74'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:46

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US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'mmHg'	System	25 Jan 2021 21:44:46

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40

US3402196
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40

Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:26:53
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:52

US3402196

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:26:53
User entered '25 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:44:52

US3402196

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:33:31

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 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:16:59
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:45:31

US3402196

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:33:31

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:16:59
User entered '25 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 21:45:31

US3402196

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:04

US3402196

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:04

US3402196

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:04

US3402196

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 15:00:04

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '06 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:32

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:11:10

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:32

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:11:10

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:32

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:32

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:32

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Placebo (Placebo)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:32

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:32

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '1'	System	26 Jan 2021 15:00:32

US3402196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '1'	System	26 Jan 2021 15:00:32

US3402196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

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Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:33:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered empty.	System	26 Jan 2021 15:02:17
DataPoint set to visible.	System	26 Jan 2021 15:00:32

US3402196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered empty.	System	26 Jan 2021 15:02:17
DataPoint set to visible.	System	26 Jan 2021 15:00:32

US3402196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '08:25'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '26 Jan 2021 08:25'	System	26 Jan 2021 15:02:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '36.2' C	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

FDA-CBER-2022-1614-1738684

US3402196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '112'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'bpm'	System	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '15'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'breaths/min'	System	26 Jan 2021 15:02:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '138'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mmHg'	System	26 Jan 2021 15:02:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '70'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mmHg'	System	26 Jan 2021 15:02:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

FDA-CBER-2022-1614-1738694

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered empty.	System	26 Jan 2021 15:02:17
DataPoint set to visible.	System	26 Jan 2021 15:00:32

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

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US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '09:30'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '26 Jan 2021 09:30'	System	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '36.7' C	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

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US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '88'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'bpm'	System	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '16'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'breaths/min'	System	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '168'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mmHg'	System	26 Jan 2021 15:02:17

US3402196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Jan 2021 15:10:03
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	26 Jan 2021 15:10:03
User entered '70' reason for change: New Information	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:03
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Jan 2021 15:02:17
User entered '30'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:02:17

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mmHg'	System	26 Jan 2021 15:02:17

US3402196

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:16

US3402196

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:16

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:37

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:37

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:37

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mRNA-1273'	System	26 Jan 2021 15:10:37
DataPoint set to visible.	System	26 Jan 2021 15:00:32

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:37

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '08:55'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:37

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '26 Jan 2021 08:55'	System	26 Jan 2021 15:10:37

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:10:37

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'ONCE'	System	26 Jan 2021 15:10:37

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 15:10:37

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:44

FDA-CBER-2022-1614-1738725

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 19Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 14:30:38
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 19Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'THE 26 JAN 2021 IS THE CORRET DATE. DEMOGRAPHIC SHEET HAS BEEN SENT TO PPD TO HAVE THIS CORRECTED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Feb 2021 15:40:18
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 19Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 14:46:45
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '08:15'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:44

FDA-CBER-2022-1614-1738727

US3402196

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '26 Jan 2021 08:15'	System	26 Jan 2021 15:00:44

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:54

US3402196

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "26-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "19-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 06:53:11
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "26-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "19-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' answered with 'The correct date is 26 Jan 2021 a DCF has been sent to have this corrected in ppd' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Feb 2021 14:26:36
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "26-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "19-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:39:59
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '08:18'	Traci Hull (b) (4) (b) (4)	26 Jan 2021 15:00:54

FDA-CBER-2022-1614-1738731

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '26 Jan 2021 08:18'	System	26 Jan 2021 15:00:54

US3402196

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

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	26 Jan 2021 15:00:58
	(b) (4)	

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

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '1'	System	26 Jan 2021 15:00:58

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 15:26:38

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '3 Feb 2021'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 15:26:38

US3402196

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 15:26:38

US3402196
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Feb 2021 15:26:38

US3402196

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 15:26:42

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '1'	System	03 Feb 2021 15:26:42

US3402196
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '1'	System	03 Feb 2021 15:26:42
DataPoint set to visible.	System	03 Feb 2021 15:26:42

US3402196
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:34:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '23 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:34:24

US3402196

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:34:24

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'OLD29'	System	23 Feb 2021 15:34:24

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '23 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '09:06'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '23 Feb 2021 09:06'	System	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '36.6' C	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '64'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'bpm'	System	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
User entered '18'	Tammy Kohn (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'breaths/min'	System	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '136'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mmHg'	System	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '78'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mmHg'	System	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '23 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '10:02'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '23 Feb 2021 10:02'	System	23 Feb 2021 15:36:13

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '36.8' C	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '63'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

US3402196
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'bpm'	System	23 Feb 2021 15:36:13

US3402196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '18'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'breaths/min'	System	23 Feb 2021 15:36:13

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '132'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mmHg'	System	23 Feb 2021 15:36:13

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '74'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:13

Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:33:31
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mmHg'	System	23 Feb 2021 15:36:13

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:48

US3402196

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '23 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:36:48

US3402196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:37:12

US3402196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:37:12

US3402196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:37:12

US3402196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'mRNA-1273'	System	23 Feb 2021 15:37:12
DataPoint set to visible.	System	03 Feb 2021 15:26:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '23 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:37:12

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '09:30'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:37:12

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '23 Feb 2021 09:30'	System	23 Feb 2021 15:37:12

US3402196
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Left Arm (LEFT ARM)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:37:12

US3402196
Folder: OL-D29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:33:31
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'ONCE'	System	23 Feb 2021 15:37:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 15:37:12

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:37:16

US3402196
Folder: OL-D29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '1'	System	23 Feb 2021 15:37:16

Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4)	02 Mar 2021 16:26:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '2 Mar 2021'	Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:26:59

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Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:26:59

US3402196
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:33:31
Comments

If Contact Not Made, please provide Comments

Audit	(b) (4), (b) (6)	Time (GMT)
Data hard locked.	Deborah Evans (6260 - evansdl1)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:26:59

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:26:48

US3402196
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:33:31
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '1'	System	02 Mar 2021 16:26:48

US3402196
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:09

US3402196

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:09

US3402196

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:09

US3402196
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:33:31
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered 'OLD57'	System	26 Mar 2021 13:32:09

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

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US3402196
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered empty.	System	26 Mar 2021 13:32:31

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

FDA-CBER-2022-1614-1738806

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

US3402196
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

US3402196
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

US3402196
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered empty.	System	26 Mar 2021 13:32:31

US3402196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered empty.	System	26 Mar 2021 13:32:31

US3402196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

US3402196
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered empty.	System	26 Mar 2021 13:32:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:31

FDA-CBER-2022-1614-1738815

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered empty.	System	26 Mar 2021 13:32:31

FDA-CBER-2022-1614-1738816

US3402196
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:33:31
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29

FDA-CBER-2022-1614-1738818

US3402196

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:39

US3402196

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:39

US3402196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:53

US3402196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:53

US3402196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
User entered '08:59'	Traci Hull (b) (4) (b) (4)	26 Mar 2021 13:32:53

US3402196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:17:29
User entered '26 Mar 2021 08:59'	System	26 Mar 2021 13:32:53

US3402196

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:33:31

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:45:14
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:16:55
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:05

US3402196
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:33:31
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth abscess, LLT: Tooth abscess - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:01:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:01:40
Data point term sent to Coder	System	04 Jan 2021 15:19:38
User entered 'ABCESSED RIGHT UPPER FIRST PREMOLAR'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '26 Dec 2020'	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User entered empty.	System	04 Jan 2021 15:19:28

US3402196
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:33:31
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:40:00
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Feb 2021 15:40:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 15:40:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:40:02
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Feb 2021 15:40:15
User entered '6 Jan 2021' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	23 Feb 2021 15:40:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:33:31
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User entered empty.	System	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'No (N)'	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28
	(b) (4)	

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Not Related (NOT RELATED)'	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Not Related (NOT RELATED)'	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Not Applicable (NOT APPLICABLE)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '1'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:45:46
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:40:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:40:15
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:19:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Tammy Kohn (b) (4)	04 Jan 2021 15:19:28

US3402196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User entered '0'	System	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35
User entered '1'	System	04 Jan 2021 15:19:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:13:35

US3402196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

AEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:44:59
User entered 'USA-US059-2021-mRNA-1273-P301000001'	System	06 Jan 2021 17:44:56
User entered 'New'	(b) (4), (b) (6)	06 Jan 2021 17:44:56

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User closed query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:10:07
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:24:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:24:24
Data point term sent to Coder	System	29 Jan 2021 21:24:12
Query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 21:23:47
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 21:23:43
User entered 'COVID 19' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 21:23:43
User opened query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 20:27:16
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 11:59:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 11:59:51
Data point term sent to Coder	System	05 Jan 2021 11:59:15
User entered 'Sars Covid 19'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:43:46
User closed query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 04:34:03
Query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' answered with 'correct as is	Traci Hull (b) (4) (b) (4)	25 Feb 2021 19:50:27
' (Site from DM).		
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	25 Feb 2021 19:49:42
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	25 Feb 2021 19:49:42
User opened query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:12:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '17 Dec 2020'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Jan 2021 18:54:50
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 18:54:50
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Jan 2021 18:54:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Apr 2021 00:03:24
User closed query 'Per source AE log and convalescent visit log end date is 25Jan2021. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 02:49:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 02:49:09
Query 'Per source AE log and convalescent visit log end date is 25Jan2021. Please verify and update accordingly. ' answered with 'updated the date to 25Jan2021' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:44:17
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:44:04
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:44:04
User entered '25 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:44:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:11
User opened query 'Per source AE log and convalescent visit log end date is 25Jan2021. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:03:04
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
User closed query 'PV Query: Per symptom log, please clarify end date as end date should be when symptoms have resolved (23 Jan 2021). The subject was still experiencing symptoms up until 22 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 19:54:51
Query 'PV Query: Per symptom log, please clarify end date as end date should be when symptoms have resolved (23 Jan 2021). The subject was still experiencing symptoms up until 22 Jan 2021.' answered with 'UPDATED' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	11 Mar 2021 20:37:09
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	11 Mar 2021 20:37:01
User entered '23 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	11 Mar 2021 20:37:01

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User opened query 'PV Query: Per symptom log, please clarify end date as end date should be when symptoms have resolved (23 Jan 2021). The subject was still experiencing symptoms up until 22 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 19:50:32
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 03:33:30
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'data updated' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 18:54:55
User entered '6 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 18:54:42
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 18:00:49
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Severity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	05 Jan 2021 11:59:04
	(b) (4)	

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:33:31
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'No (N)'	Jennifer Molstead (b) (4)	05 Jan 2021 11:59:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:33:31
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:38:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	05 Jan 2021 11:59:04
	(b) (4)	

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Generated On: 11 Aug 2021 22:33:31

None

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:33:31
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 03:33:36
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' answered with 'data updated' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 18:55:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 18:54:42
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 18:01:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 11 Aug 2021 22:33:31
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:32:27
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 11:59:04

US3402196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	05 Jan 2021 11:59:04

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 19:49:42
User entered '0'	System	05 Jan 2021 11:59:04

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:45:14
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:09
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 Aug 2020 16:39:11
	(b) (4)	

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 10:00:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 10:00:19
Data point term sent to Coder	System	03 Aug 2020 16:40:38
User entered 'valsartan'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'hypertension'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '320'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:07:35
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 16:39:52
User entered 'un UNK 2017'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

FDA-CBER-2022-1614-1738909

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

FDA-CBER-2022-1614-1738911

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 16:39:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 16:39:52

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 16:39:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 16:43:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 16:43:07
Data point term sent to Coder	System	03 Aug 2020 16:41:41
User entered 'hydrochlorothiazide'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

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US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Indication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'hypertension'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '25'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:33:31
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:07:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 16:40:45
User entered 'un UNK 2017'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

FDA-CBER-2022-1614-1738927

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 16:40:45

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 16:40:45

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 16:40:45

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 00:52:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 00:52:35
Data point term sent to Coder	System	04 Jan 2021 15:21:39
User entered 'AMOXICILLIN'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:21:16

FDA-CBER-2022-1614-1738935

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'ABCESSED TOOTH'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '875'	Tammy Kohn (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'mg (mg)'	Tammy Kohn (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Tammy Kohn (b) (4)	04 Jan 2021 15:21:16
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'twice daily (BID)'	Tammy Kohn (b) (4)	04 Jan 2021 15:21:16
	(b) (4)	

FDA-CBER-2022-1614-1738941

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Tammy Kohn (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Tammy Kohn (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '26 Dec 2020'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '0'	Tammy Kohn (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:52
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Feb 2021 15:44:13
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Feb 2021 15:44:13
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:37:55
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:44:13
User entered '5 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Feb 2021 15:44:13
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:02:31
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	10 Feb 2021 13:45:51
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	10 Feb 2021 13:45:44
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:29:51
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	04 Jan 2021 15:21:16

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User entered '2'	System	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User entered '1'	System	04 Jan 2021 15:21:16

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:36
User entered '804 (804)'	System	04 Jan 2021 15:21:16

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US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:46:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:46:45
Data point term sent to Coder	System	05 Jan 2021 12:01:15
User entered 'prednisone'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

FDA-CBER-2022-1614-1738953

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Sars Covid 19'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '40'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

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US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Jennifer Molstead (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '30 Dec 2020'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:03:59
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:58:38
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	24 Mar 2021 13:11:59
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	24 Mar 2021 13:11:43
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	24 Mar 2021 13:11:43
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:34:00
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

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US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:00
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	24 Mar 2021 13:11:43
User entered '08 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	24 Mar 2021 13:11:43
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:38:23
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	05 Jan 2021 12:00:17

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User entered '1'	System	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User entered '1'	System	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User entered '804 (804)'	System	05 Jan 2021 12:00:17

US3402196

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:33:31

Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:30:26
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:39:06
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 16:41:09

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'USA-US059-2021-MRNA-1273-P301000001'	System	06 Jan 2021 17:44:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1738978

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1738979

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Frank'	System	06 Jan 2021 17:44:56

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Eder'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered '1290 Upper Front Street'	System	06 Jan 2021 17:44:56

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Binghamton'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'NY'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1738984

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered '13901'	System	06 Jan 2021 17:44:56

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 21:22:37
User entered 'US'	System	06 Jan 2021 17:54:07

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 21:22:47
User entered '2'	System	26 Jan 2021 03:34:06
User entered '1'	System	06 Jan 2021 17:54:07

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'USA-US059-2021-MRNA-1273-P301000001'	System	06 Jan 2021 17:44:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1738989

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1738993

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1738994

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1738995

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Frank'	System	06 Jan 2021 17:44:56

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Eder'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered '1290 Upper Front Street'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Binghamton'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1738999

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'NY'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered '13901'	System	06 Jan 2021 17:44:56

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 21:22:37
User entered 'US'	System	06 Jan 2021 17:54:07

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 21:22:47
User entered '2'	System	26 Jan 2021 03:34:06
User entered '1'	System	06 Jan 2021 17:54:07

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:33:31

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
User entered '06/Jan/2021 17:54'	System	06 Jan 2021 17:54:07

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:33:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 21:22:37
User entered '1'	(b) (4), (b) (6)	06 Jan 2021 17:54:07

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'USA-US059-2021-MRNA-1273-P301000001'	System	06 Jan 2021 17:44:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739007

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739008

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739009

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Frank'	System	06 Jan 2021 17:44:56

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Eder'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered '1290 Upper Front Street'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739016

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Binghamton'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'NY'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739018

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered '13901'	System	06 Jan 2021 17:44:56

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 21:22:37
User entered 'US'	System	06 Jan 2021 17:54:07

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 21:22:47
User entered '2'	System	26 Jan 2021 03:34:06
User entered '1'	System	06 Jan 2021 17:54:07

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
User entered '25/Jan/2021 22:34'	System	26 Jan 2021 03:34:06

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:33:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 21:22:37
User entered '1'	(b) (4), (b) (6)	26 Jan 2021 03:34:06

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'USA-US059-2021-MRNA-1273-P301000001'	System	06 Jan 2021 17:44:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739025

Death

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739026

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739028

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739030

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'No (N)'	System	06 Jan 2021 17:44:56

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US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Frank'	System	06 Jan 2021 17:44:56

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Eder'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739033

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered '1290 Upper Front Street'	System	06 Jan 2021 17:44:56

FDA-CBER-2022-1614-1739034

US3402196
Folder: SAE USA-US059-2021-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 11 Aug 2021 22:33:31
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'Binghamton'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered 'NY'	System	06 Jan 2021 17:44:56

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Jan 2021 17:54:01
User entered '13901'	System	06 Jan 2021 17:44:56

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:01:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 21:22:37
User entered 'US'	System	06 Jan 2021 17:54:07

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 21:22:47
User entered '2'	System	26 Jan 2021 03:34:06
User entered '1'	System	06 Jan 2021 17:54:07

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:33:31

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
User entered '12/Mar/2021 15:22'	System	12 Mar 2021 21:22:47

US3402196

Folder: SAE USA-US059-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:33:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:46:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:01:10
User entered '1'	(b) (4), (b) (6)	12 Mar 2021 21:22:47