US3402232 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

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US3402232
Form: Participant Creation
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

Participant ID	US3402232

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-1749900

US3402232
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-1749901

US3402232
Folder: Screening
Form: Demographics
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	33
Age Units	YEARS
Age (Derived)	33
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

FDA-CBER-2022-1614-1749902

US3402232
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Date of Informed Consent *(dd MMM yyyy)*	5 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

FDA-CBER-2022-1614-1749903

US3402232
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Did the participant meet all eligibility criteria?	Yes ■ No ☐

FDA-CBER-2022-1614-1749904

US3402232
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Were any significant conditions reported?	Yes ☐ No ☒

FDA-CBER-2022-1614-1749905

US3402232
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	5 AUG 2020
Time of assessment *(00:00-23:59)*	08:03 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 08:03
Height *(xxx.x)*	198.1 cm
Weight *(xxx.x)*	106.6 kg
BMI *(xxx.x)*	27.16366 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)	

FDA-CBER-2022-1614-1749906

US3402232
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	5 AUG 2020

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

FDA-CBER-2022-1614-1749907

US3402232
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

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

Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

US3402232
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 17:17:20**
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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

FDA-CBER-2022-1614-1749909

US3402232
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	5 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-1749910

US3402232
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

What was the date of randomization? *(dd MMM yyyy)*	05 AUG 2020
What was the participant's randomization number?	100972
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 ■

FDA-CBER-2022-1614-1749911

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-1749912

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

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)*	5 AUG 2020
Time of assessment *(00:00-23:59)*	08:03 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 08:03
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1749913

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

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)*	5 AUG 2020
Time of assessment *(00:00-23:59)*	09:12 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 09:12
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ● Axillary ○ Other ○
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1749914

US3402232
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	5 AUG 2020

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

FDA-CBER-2022-1614-1749915

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

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)*	5 AUG 2020
What was the treatment time? *(00:00-23:59)*	08:41 (24 HR)
Treatment Date and Time (derived)	5 AUG 2020 08:41
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

FDA-CBER-2022-1614-1749916

US3402232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	5 AUG 2020
Collection time *(00:00-23:59)*	08:30 (24 HR)
Collection date and time (derived)	5 AUG 2020 08:30

FDA-CBER-2022-1614-1749917

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Collection date *(dd MMM yyyy)*			5 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:20	5 AUG 2020 08:20
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-1749918

US3402232
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1749919

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33

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**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 AUG 2020 09:13
PC Open Date & Time	05 AUG 2020 09:01
PC Close Date & Time	05 AUG 2020 11:31

FDA-CBER-2022-1614-1749920

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**	97.6 °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 AUG 2020 12:57
PC Open Date & Time	05 AUG 2020 12:26
PC Close Date & Time	06 AUG 2020 11:59

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33

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**	97.1 °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	06 AUG 2020 16:25
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 AUG 2020 22:14
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 AUG 2020 22:43
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33

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**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 AUG 2020 13:22
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33

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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	10 AUG 2020 12:06
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 AUG 2020 20:37
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33

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	05 AUG 2020 09:14
PC Open Date & Time	05 AUG 2020 09:01
PC Close Date & Time	05 AUG 2020 11:31

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US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	05 AUG 2020 12:57
PC Open Date & Time	05 AUG 2020 12:26
PC Close Date & Time	06 AUG 2020 11:59

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33

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	06 AUG 2020 16:26
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-1749930

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33

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	07 AUG 2020 22:14
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-1749931

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33

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	08 AUG 2020 22:43
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-1749932

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	09 AUG 2020 13:22
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33

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	10 AUG 2020 12:07
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-1749934

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	11 AUG 2020 20:37
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-1749935

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 ☐

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 AUG 2020 09:15
PC Open Date & Time	05 AUG 2020 09:01
PC Close Date & Time	05 AUG 2020 11:31

FDA-CBER-2022-1614-1749937

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 ☐

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 AUG 2020 12:58
PC Open Date & Time	05 AUG 2020 12:26
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-1749939

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33

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 ■

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US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33

	Yes
PC Time stamp	06 AUG 2020 16:26
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-1749941

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33

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 ■

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33

	Yes
PC Time stamp	07 AUG 2020 22:14
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 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 ■

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33

	Yes ☐
PC Time stamp	08 AUG 2020 22:43
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

TIMEPOINT	DAY 5
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33

	Yes ☐
PC Time stamp	09 AUG 2020 13:22
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-1749947

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 6
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-1749948

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33

	Yes
PC Time stamp	10 AUG 2020 12:07
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-1749949

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 ■

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33

	Yes ☐
PC Time stamp	11 AUG 2020 20:37
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-1749951

US3402232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1749952

US3402232
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1749953

US3402232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1749954

US3402232
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1749955

US3402232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1749956

US3402232
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1749957

US3402232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-1749958

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	2 SEP 2020
Time of assessment *(00:00-23:59)*	07:52 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 07:52
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	52 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1749959

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	2 SEP 2020
Time of assessment *(00:00-23:59)*	08:59 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 08:59
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1749960

US3402232
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	2 SEP 2020

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

FDA-CBER-2022-1614-1749961

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

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)*	2 SEP 2020
What was the treatment time? *(00:00-23:59)*	08:25 (24 HR)
Treatment Date and Time (derived)	2 SEP 2020 08:25
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

FDA-CBER-2022-1614-1749962

US3402232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	2 SEP 2020
Collection time *(00:00-23:59)*	08:05 (24 HR)
Collection date and time (derived)	2 SEP 2020 08:05

FDA-CBER-2022-1614-1749963

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Collection date *(dd MMM yyyy)*			2 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:04	2 SEP 2020 08:04
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-1749964

US3402232
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1749965

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 SEP 2020 09:00
PC Open Date & Time	02 SEP 2020 08:45
PC Close Date & Time	02 SEP 2020 11:15

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**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 SEP 2020 13:41
PC Open Date & Time	02 SEP 2020 12:10
PC Close Date & Time	03 SEP 2020 11:59

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °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	03 SEP 2020 12:02
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °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 23:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 SEP 2020 06:08
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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.

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °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	06 SEP 2020 12:10
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 6

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 SEP 2020 21:55
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 SEP 2020 02:52
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33

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	02 SEP 2020 09:00
PC Open Date & Time	02 SEP 2020 08:45
PC Close Date & Time	02 SEP 2020 11:15

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33

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	02 SEP 2020 13:41
PC Open Date & Time	02 SEP 2020 12:10
PC Close Date & Time	03 SEP 2020 11:59

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	1
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 12:03
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33

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	04 SEP 2020 23:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

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US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33

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 SEP 2020 06:08
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33

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

FDA-CBER-2022-1614-1749979

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33

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	07 SEP 2020 21:55
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-1749980

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33

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 SEP 2020 02:52
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-1749981

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 ☐

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	02 SEP 2020 09:01
PC Open Date & Time	02 SEP 2020 08:45
PC Close Date & Time	02 SEP 2020 11:15

FDA-CBER-2022-1614-1749983

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 ☐

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	02 SEP 2020 13:41
PC Open Date & Time	02 SEP 2020 12:10
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-1749985

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 ■

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33

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

FDA-CBER-2022-1614-1749987

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1749988

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33

	Yes
PC Time stamp	04 SEP 2020 23:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-1749989

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 ■

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33

	Yes
PC Time stamp	06 SEP 2020 06:08
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-1749991

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 ■

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33

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

FDA-CBER-2022-1614-1749993

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 ■

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33

	Yes ☐
PC Time stamp	07 SEP 2020 21:55
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-1749995

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 ■

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33

	Yes
PC Time stamp	09 SEP 2020 02:52
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-1749997

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(8)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 8
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 ☐
PC Time Stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-1749998

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(9)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 9
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 ☐
PC Time Stamp	
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-1749999

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-1750000

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-1750001

US3402232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3402232
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750003

US3402232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1750004

US3402232
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750005

US3402232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1750006

US3402232
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:20**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750007

US3402232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-1750008

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	30 SEP 2020
Time of assessment *(00:00-23:59)*	14:38 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 14:38
Temperature *(xxx.x)*	36.2 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-1750009

US3402232
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

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.

US3402232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	30 SEP 2020
Collection time *(00:00-23:59)*	14:44 (24 HR)
Collection date and time (derived)	30 SEP 2020 14:44

US3402232
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 17:17:21**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750012

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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	05 OCT 2020 00:33:57
Patient Cloud Open Date & Time	05 OCT 2020 00:01
Patient Cloud Close Date & Time	09 OCT 2020 23:59

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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	12 OCT 2020 07:14:40
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 06:35:25
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

FDA-CBER-2022-1614-1750015

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 ☐

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 10:36:18
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

FDA-CBER-2022-1614-1750018

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

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

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 14:35:37
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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	04 DEC 2020 04:09:12
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 05:52:20
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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	18 DEC 2020 03:03:23
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

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

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

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

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 02:26:00
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 08:48:39
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 01:20:25
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 04:51:46
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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	09 FEB 2021 06:06:07
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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	12 FEB 2021 01:04:33
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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 ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 04:58:37
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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	26 FEB 2021 00:01:28
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

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 ☐

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 18:57:04
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

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 ☐

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	26 MAR 2021 04:16:50
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3402232
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 17:24:33

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		12 MAR 2021 18:56:53

FDA-CBER-2022-1614-1750045

US3402232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **08 Mar 2021 22:21:46**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3402232
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **08 Mar 2021 22:21:46**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750047

US3402232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

US3402232
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750049

US3402232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-1750050

US3402232
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750051

US3402232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1750052

US3402232
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750053

US3402232
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 22:53:10**
Generated On: 09 Jun 2021 17:24:33

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

FDA-CBER-2022-1614-1750054

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 22:53:10**
Generated On: 09 Jun 2021 17:24:33

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)	

FDA-CBER-2022-1614-1750055

US3402232
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 22:53:10**
Generated On: 09 Jun 2021 17:24:33

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.

FDA-CBER-2022-1614-1750056

US3402232
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Apr 2021 22:53:10**
Generated On: 09 Jun 2021 17:24:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	23 FEB 2021
Collection time *(00:00-23:59)*	14:19 (24 HR)
Collection date and time (derived)	23 FEB 2021 14:19

US3402232
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 22:53:10**
Generated On: 09 Jun 2021 17:24:33

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1750058

US3402232
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33

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*	

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Is the participant continuing to the next visit?	Yes ☐ No ☐
Continuing Flag	

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID-19 Contact
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

Date of Contact	26 MAR 2021
Time of Contact	14:00
Date and Time of Contact (derived)	26 MAR 2021 14:00
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ■ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ■ No ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1750062

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	18 MAR 2021
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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1750066

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	19 MAR 2021
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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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 MAR 2021
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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1750074

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	21 MAR 2021
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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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 MAR 2021
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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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 MAR 2021
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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1750086

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	24 MAR 2021
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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1750090

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	25 MAR 2021
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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1750094

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	26 MAR 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	36.9 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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1750098

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	27 MAR 2021
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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	28 MAR 2021
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

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-2022-1614-1750106

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	29 MAR 2021
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

	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 ☐

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Data signed: (b) (4) **26 Apr 2021 22:52:33**
Generated On: 09 Jun 2021 17:24:33

Date of Visit	26 MAR 2021
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	26 MAR 2021
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

Did the subject have Respiratory Rates ≥ 30 per Minute?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Respiratory Rate	
Did the subject have Heart Rate ≥ 125 beats per minute	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Heart Rate	
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Oxygen Saturation	
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
PaO2	
Did the subject have Respiratory failure?	Yes ☐ No ■
Start Date	
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?	Yes ☐ No ■
Start Date	

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

Ventilator Support:	
High-Flow Oxygen?	Yes ☐ No ■
Start Date	
End Date	
Non-Invasive Ventilation?	Yes ☐ No ■
Start Date	
End Date	
Mechanical Ventilation?	Yes ☐ No ■
Start Date	
End Date	
ECMO?	Yes ☐ No ■
Start Date	
End Date	
Evidence of Shock:	
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ☐ No ■
Start Date	
End Date	
Evidence of Shock Requires Vasopressors	Yes ☐ No ■
Start Date	
End Date	
Acute Renal Dysfunction?	Yes ☐ No ■
Start Date	

Hepatic Dysfunction?	Yes ☐ No ■
Start Date	
Neurologic Dysfunction?	Yes ☐ No ■
Start Date	
Evidence of Pneumonia:	
Clinical Evidence	Yes ☐ No ■
Date of Assessment	
Radiographical Evidence	Yes ☐ No ■
Date of Assessment	

Admission to an intensive care unit due to SARS-CoV-2	Yes ☐ No ■
Start Date	
End Date	

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection
Data signed: (b) (4) **03 May 2021 22:58:20**
Generated On: 09 Jun 2021 17:24:33

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

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US3402232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

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	SICKD1

FDA-CBER-2022-1614-1750115

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	26 MAR 2021
Time of assessment *(00:00-23:59)*	14:13 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 14:13
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402232
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

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.

FDA-CBER-2022-1614-1750117

US3402232
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 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	26 MAR 2021

FDA-CBER-2022-1614-1750118

US3402232
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33

Was this visit performed?	Yes ☐ No ☐
Visit date (dd MMM yyyy)	_____
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☐
Folder OID	_____

FDA-CBER-2022-1614-1750119

US3402232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33

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)	

FDA-CBER-2022-1614-1750120

Was the physical examination performed?	Yes ☐ No ☐
Date of examination *(dd MMM yyyy)*	_____

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

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ☐ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	_____

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	12 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

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)*	12 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	
Continuing with mRNA-1273	

FDA-CBER-2022-1614-1750124

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	12 JAN 2021
Collection time *(00:00-23:59)*	13:45 (24 HR)
Collection date and time (derived)	12 JAN 2021 13:45

FDA-CBER-2022-1614-1750125

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	12 JAN 2021
Collection time *(00:00 - 23:59)*	13:47
Collection Date and Time (derived)	12 JAN 2021 13:47

US3402232
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **08 Apr 2021 23:32:39**
Generated On: 09 Jun 2021 17:24:33

Did the participant experience any adverse events?	Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-1750127

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **15 Apr 2021 00:03:55**
Generated On: 09 Jun 2021 17:24:33

AEID	USA-US059-2021-MRNA-1273-P30 1000013
Adverse event	SARS COVID 2
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ■ No ☐
Start date *(dd MMM yyyy)*	18 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	26 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	True
Concomitant Medication	False
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

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **15 Apr 2021 00:03:55**
Generated On: 09 Jun 2021 17:24:33

	SUBJECT DEVELOPED COVID SYMPTOMS 18 MAR 2021. SUBJECT ADVISED SITE OF SYMPTOMS 24MAR2021, AND WAS SEEN FOR ILLNESS VISIT 26MAR2021. AFTER BEING FOLLOWED FOR 4 DAYS SUBJECT THEN WITHDREW CONSENT FROM TRIAL.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

FDA-CBER-2022-1614-1750130

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **08 Apr 2021 23:32:39**
Generated On: 09 Jun 2021 17:24:33

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-1750131

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **08 Apr 2021 23:32:39**
Generated On: 09 Jun 2021 17:24:33

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☐ No ■
Indication	DIETARY SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ■ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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 2016
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 ■

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **08 Apr 2021 23:32:39**
Generated On: 09 Jun 2021 17:24:33

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	PAIN AT INJECTION SITE
Dose per administration	200
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)*	03 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	09 SEP 2020
Was this medication taken for solicited event?	Yes ■ No ☐
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3402232
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **08 Apr 2021 23:32:39**
Generated On: 09 Jun 2021 17:24:33

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-1750136

US3402232
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 17:24:33

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	_____

FDA-CBER-2022-1614-1750137

US3402232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

Date of study discontinuation/completion *(dd MMM yyyy)*	26 MAR 2021
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	SUBJECT REFUSED TO COMPLY WITH CONVALESCENT PERIOD REQUIREMENTS .
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-1750138

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

SAEID	USA-US059-2021-MRNA-1273-P301000013
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)	2

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form (1)
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

SAEID	USA-US059-2021-MRNA-1273-P301000013
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)	2
Date of submission (Pre-filled from custom function)	05/APR/2021 13:21
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

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form (2)
Data signed: (b) (4) **26 Apr 2021 22:52:34**
Generated On: 09 Jun 2021 17:24:33

SAEID	USA-US059-2021-MRNA-1273-P301000013
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)	2
Date of submission (Pre-filled from custom function)	13/APR/2021 12:06
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

US3402232 (Prod: Meridian Clinical Research, LLC)

US3402232
Form: Participant Creation
Generated On: 09 Jun 2021 17:24:33
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'US3402232'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:14:15

FDA-CBER-2022-1614-1750143

US3402232
Form: Participant Creation
Generated On: 09 Jun 2021 17:24:33

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750144

US3402232
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:12

FDA-CBER-2022-1614-1750145

US3402232
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:14:16

FDA-CBER-2022-1614-1750146

US3402232
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:12

US3402232
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered 'SCRN'	System	05 Aug 2020 16:38:12

FDA-CBER-2022-1614-1750148

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered (b) (6) 1986'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:14:17

FDA-CBER-2022-1614-1750149

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '33'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750150

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered 'YEARS'	System	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750151

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered '33'	System	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750152

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Male (M)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750153

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '1'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750155

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750156

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750157

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750158

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750159

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750160

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750161

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750162

US3402232
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:24:33
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:38:34

FDA-CBER-2022-1614-1750163

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750164

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered 'Aug 2020'	System	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750165

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered '2020'	System	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750166

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Amendment 1 (1)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750167

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 12:59:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 12:59:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:59:02
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 12:58:56
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750168

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750169

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750170

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:58:56

FDA-CBER-2022-1614-1750171

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:14:16

FDA-CBER-2022-1614-1750172

US3402232
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:24:33
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered '1'	System	05 Aug 2020 12:59:06

FDA-CBER-2022-1614-1750173

US3402232
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 17:24:33
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:59:06

FDA-CBER-2022-1614-1750174

US3402232
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 17:24:33
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:31

FDA-CBER-2022-1614-1750175

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750176

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750177

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:03'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750178

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered '5 Aug 2020 08:03'	System	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750179

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '198.1' cm	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40
DataPoint set to visible.	System	05 Aug 2020 12:59:06

FDA-CBER-2022-1614-1750180

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '106.6' kg	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40
DataPoint set to visible.	System	05 Aug 2020 12:59:06

FDA-CBER-2022-1614-1750181

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
Amendment Manager: User entered '27.16366'	System	16 Sep 2020 23:43:30
User entered '27.2'	System	05 Aug 2020 16:40:40
DataPoint set to visible.	System	05 Aug 2020 12:59:06

FDA-CBER-2022-1614-1750182

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered 'kg/m2'	System	05 Aug 2020 16:40:40
DataPoint set to visible.	System	05 Aug 2020 12:59:06

FDA-CBER-2022-1614-1750183

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:34
User entered '36.4' C	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750184

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:34
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750185

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:34
User entered '56'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered 'bpm'	System	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750188

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:34
User entered '16'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750189

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered 'breaths/min'	System	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750190

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:34
User entered '118'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered 'mmHg'	System	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750192

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:34
User entered '72'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:40:40

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User entered 'mmHg'	System	05 Aug 2020 16:40:40

FDA-CBER-2022-1614-1750194

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10

FDA-CBER-2022-1614-1750195

US3402232
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10

FDA-CBER-2022-1614-1750196

US3402232
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:03

FDA-CBER-2022-1614-1750197

US3402232
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
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 12:42:18
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 12:45:08
User entered '5 Aug 2020'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:03

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750199

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750200

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750201

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750202

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750203

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750206

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750207

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750208

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750209

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750210

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750211

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750212

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750213

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750214

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750215

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750216

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '1'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750217

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750218

US3402232
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:24:33
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:35:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:39:11

FDA-CBER-2022-1614-1750219

US3402232
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:16

FDA-CBER-2022-1614-1750220

US3402232
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:16

FDA-CBER-2022-1614-1750221

US3402232
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
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 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:16

FDA-CBER-2022-1614-1750222

US3402232
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'VISIT1'	System	05 Aug 2020 16:41:16

FDA-CBER-2022-1614-1750223

US3402232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:24:33
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:14:18

FDA-CBER-2022-1614-1750224

US3402232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:24:33
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:09:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:09:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 12:14:18
User entered '100972' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:14:18

FDA-CBER-2022-1614-1750225

US3402232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:24:33
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:14:18

FDA-CBER-2022-1614-1750226

US3402232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:33

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 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:44

US3402232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:33

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 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:44

US3402232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:24:33
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:44

FDA-CBER-2022-1614-1750229

US3402232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:24:33
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:44

FDA-CBER-2022-1614-1750230

US3402232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:24:33
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:41:44

FDA-CBER-2022-1614-1750231

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:24:33
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:52
User entered '198.7' cm	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750232

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:24:33
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:52
User entered '106.6' kg	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750233

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:24:33
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:52
User entered '198.7' cm	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750234

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:24:33
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:52
User entered '106.6' kg	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750235

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750236

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750237

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750238

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:03'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750239

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '5 Aug 2020 08:03'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750240

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '36.4' C	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750241

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750242

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750243

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '56'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750244

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'bpm'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750245

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '16'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750246

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'breaths/min'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750247

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '118'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750248

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750249

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '72'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750250

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750251

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:24:33
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:52
User entered '198.7' cm	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750252

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:24:33
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Dec 2020 16:49:52
User entered '106.6' kg	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750253

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750254

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750255

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750256

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 19:47:23
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes' (Site from System).	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:59
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	05 Aug 2020 16:43:49
User entered '09:12'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '5 Aug 2020 09:12'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750258

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '36.3' C	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750259

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750260

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750261

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '59'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750262

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'bpm'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750263

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '16'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750264

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'breaths/min'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750265

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '124'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750266

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750267

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '78'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750268

US3402232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	05 Aug 2020 16:43:49

FDA-CBER-2022-1614-1750269

US3402232
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:12

FDA-CBER-2022-1614-1750270

US3402232
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:12

FDA-CBER-2022-1614-1750271

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750272

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750273

US3402232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:33

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 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:59:27

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750275

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750276

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:41'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750277

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '5 Aug 2020 08:41'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750278

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750279

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'ONCE'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750280

US3402232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750281

US3402232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:32

FDA-CBER-2022-1614-1750282

US3402232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:32

FDA-CBER-2022-1614-1750283

US3402232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:30'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:32

FDA-CBER-2022-1614-1750284

US3402232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '5 Aug 2020 08:30'	System	05 Aug 2020 16:44:32

FDA-CBER-2022-1614-1750285

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '5 Aug 2020'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750286

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:24:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750287

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750288

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:20'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750289

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '5 Aug 2020 08:20'	System	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750290

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:24:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750291

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750292

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750293

US3402232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered empty.	System	05 Aug 2020 16:44:52

FDA-CBER-2022-1614-1750294

US3402232
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:45:19

FDA-CBER-2022-1614-1750295

US3402232
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	05 Aug 2020 16:45:19

FDA-CBER-2022-1614-1750296

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750297

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:13:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'd64d9ce0-1ae3-4631-9d7d-78da9d768efb'	System	05 Aug 2020 13:13:51
User entered 'Yes (Y)'	System	05 Aug 2020 13:13:51

FDA-CBER-2022-1614-1750298

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:13:31', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'd64d9ce0-1ae3-4631-9d7d-78da9d768efb'	System	05 Aug 2020 13:13:51
User entered '97.3'	System	05 Aug 2020 13:13:51

FDA-CBER-2022-1614-1750299

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:13:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'd64d9ce0-1ae3-4631-9d7d-78da9d768efb'	System	05 Aug 2020 13:13:51
User entered 'No (N)'	System	05 Aug 2020 13:13:51

FDA-CBER-2022-1614-1750300

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:13:48', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'd64d9ce0-1ae3-4631-9d7d-78da9d768efb'	System	05 Aug 2020 13:13:51
User entered '05 Aug 2020 09:13'	System	05 Aug 2020 13:13:51

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 09:01'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750302

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 11:31'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750303

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750304

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:11', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'fa4dd31f-94f4-4cda-91ca-800a185cc75f'	System	05 Aug 2020 16:57:25
User entered 'Yes (Y)'	System	05 Aug 2020 16:57:25

FDA-CBER-2022-1614-1750305

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'fa4dd31f-94f4-4cda-91ca-800a185cc75f'	System	05 Aug 2020 16:57:25
User entered '97.6'	System	05 Aug 2020 16:57:25

FDA-CBER-2022-1614-1750306

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:19', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'fa4dd31f-94f4-4cda-91ca-800a185cc75f'	System	05 Aug 2020 16:57:25
User entered 'No (N)'	System	05 Aug 2020 16:57:25

FDA-CBER-2022-1614-1750307

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:22', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'fa4dd31f-94f4-4cda-91ca-800a185cc75f'	System	05 Aug 2020 16:57:25
User entered '05 Aug 2020 12:57'	System	05 Aug 2020 16:57:25

FDA-CBER-2022-1614-1750308

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 12:26'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750309

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750310

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 2'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750311

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:25:32', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0221bd48-9bee-4586-a3c8-1468330cc885'	System	06 Aug 2020 20:25:44
User entered 'Yes (Y)'	System	06 Aug 2020 20:25:44

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:25:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0221bd48-9bee-4586-a3c8-1468330cc885'	System	06 Aug 2020 20:25:44
User entered '97.1'	System	06 Aug 2020 20:25:44

FDA-CBER-2022-1614-1750313

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:25:38', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0221bd48-9bee-4586-a3c8-1468330cc885'	System	06 Aug 2020 20:25:44
User entered 'No (N)'	System	06 Aug 2020 20:25:44

FDA-CBER-2022-1614-1750314

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:25:41', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0221bd48-9bee-4586-a3c8-1468330cc885'	System	06 Aug 2020 20:25:44
User entered '06 Aug 2020 16:25'	System	06 Aug 2020 20:25:44

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750316

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750317

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 3'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750318

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '20505840-5801-41d0-9e00-c95cb65812e0'	System	08 Aug 2020 02:14:13
User entered 'Yes (Y)'	System	08 Aug 2020 02:14:13

FDA-CBER-2022-1614-1750319

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:04', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '20505840-5801-41d0-9e00-c95cb65812e0'	System	08 Aug 2020 02:14:13
User entered '98.1'	System	08 Aug 2020 02:14:13

FDA-CBER-2022-1614-1750320

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:06', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '20505840-5801-41d0-9e00-c95cb65812e0'	System	08 Aug 2020 02:14:13
User entered 'No (N)'	System	08 Aug 2020 02:14:13

FDA-CBER-2022-1614-1750321

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:08', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '20505840-5801-41d0-9e00-c95cb65812e0'	System	08 Aug 2020 02:14:13
User entered '07 Aug 2020 22:14'	System	08 Aug 2020 02:14:13

FDA-CBER-2022-1614-1750322

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750323

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750324

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 4'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750325

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:11', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9c5a9746-69de-41fb-b074-6ba33395695e'	System	09 Aug 2020 02:43:26
User entered 'Yes (Y)'	System	09 Aug 2020 02:43:26

FDA-CBER-2022-1614-1750326

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9c5a9746-69de-41fb-b074-6ba33395695e'	System	09 Aug 2020 02:43:26
User entered '98.4'	System	09 Aug 2020 02:43:26

FDA-CBER-2022-1614-1750327

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:19', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9c5a9746-69de-41fb-b074-6ba33395695e'	System	09 Aug 2020 02:43:26
User entered 'No (N)'	System	09 Aug 2020 02:43:26

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:21', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9c5a9746-69de-41fb-b074-6ba33395695e'	System	09 Aug 2020 02:43:26
User entered '08 Aug 2020 22:43'	System	09 Aug 2020 02:43:26

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750330

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750331

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 5'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750332

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:08', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '10c0857c-4136-45ef-a3d5-adcdc02a4c35'	System	09 Aug 2020 17:22:20
User entered 'Yes (Y)'	System	09 Aug 2020 17:22:20

FDA-CBER-2022-1614-1750333

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '10c0857c-4136-45ef-a3d5-adcdc02a4c35'	System	09 Aug 2020 17:22:20
User entered '98.1'	System	09 Aug 2020 17:22:20

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:15', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '10c0857c-4136-45ef-a3d5-adcdc02a4c35'	System	09 Aug 2020 17:22:20
User entered 'No (N)'	System	09 Aug 2020 17:22:20

FDA-CBER-2022-1614-1750335

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '10c0857c-4136-45ef-a3d5-adcdc02a4c35'	System	09 Aug 2020 17:22:20
User entered '09 Aug 2020 13:22'	System	09 Aug 2020 17:22:20

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750337

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750338

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 6'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750339

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:06:43', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c9bf7de2-3ba1-4ab9-b4e3-901845aae980'	System	10 Aug 2020 16:07:01
User entered 'Yes (Y)'	System	10 Aug 2020 16:07:01

FDA-CBER-2022-1614-1750340

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:06:48', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c9bf7de2-3ba1-4ab9-b4e3-901845aae980'	System	10 Aug 2020 16:07:01
User entered '98.6'	System	10 Aug 2020 16:07:01

FDA-CBER-2022-1614-1750341

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:06:56', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c9bf7de2-3ba1-4ab9-b4e3-901845aae980'	System	10 Aug 2020 16:07:01
User entered 'No (N)'	System	10 Aug 2020 16:07:01

FDA-CBER-2022-1614-1750342

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:06:58', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c9bf7de2-3ba1-4ab9-b4e3-901845aae980'	System	10 Aug 2020 16:07:01
User entered '10 Aug 2020 12:06'	System	10 Aug 2020 16:07:01

FDA-CBER-2022-1614-1750343

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750344

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750345

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 7'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750346

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:08', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '341a237d-8cd9-4577-b103-070ec12363d5'	System	12 Aug 2020 00:37:23
User entered 'Yes (Y)'	System	12 Aug 2020 00:37:23

FDA-CBER-2022-1614-1750347

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '341a237d-8cd9-4577-b103-070ec12363d5'	System	12 Aug 2020 00:37:23
User entered '98.4'	System	12 Aug 2020 00:37:23

FDA-CBER-2022-1614-1750348

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:15', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '341a237d-8cd9-4577-b103-070ec12363d5'	System	12 Aug 2020 00:37:23
User entered 'No (N)'	System	12 Aug 2020 00:37:23

FDA-CBER-2022-1614-1750349

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '341a237d-8cd9-4577-b103-070ec12363d5'	System	12 Aug 2020 00:37:23
User entered '11 Aug 2020 20:37'	System	12 Aug 2020 00:37:23

FDA-CBER-2022-1614-1750350

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750351

US3402232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750352

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750353

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:14:32', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '98792345-aa25-41c7-96e8-798037cef557'	System	05 Aug 2020 13:14:54
User entered 'None (1)'	System	05 Aug 2020 13:14:54

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:14:44', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '98792345-aa25-41c7-96e8-798037cef557'	System	05 Aug 2020 13:14:54
User entered 'No (N)'	System	05 Aug 2020 13:14:54

FDA-CBER-2022-1614-1750355

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:14:46', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '98792345-aa25-41c7-96e8-798037cef557'	System	05 Aug 2020 13:14:54
User entered 'No (N)'	System	05 Aug 2020 13:14:54

FDA-CBER-2022-1614-1750356

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:14:49', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '98792345-aa25-41c7-96e8-798037cef557'	System	05 Aug 2020 13:14:54
User entered 'None (1)'	System	05 Aug 2020 13:14:54

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:14:52', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '98792345-aa25-41c7-96e8-798037cef557'	System	05 Aug 2020 13:14:54
User entered '05 Aug 2020 09:14'	System	05 Aug 2020 13:14:54

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 09:01'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750359

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 11:31'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750360

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750361

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:30', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '646c7717-6da6-450e-8392-5b98858814b3'	System	05 Aug 2020 16:57:46
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 16:57:46

FDA-CBER-2022-1614-1750362

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '646c7717-6da6-450e-8392-5b98858814b3'	System	05 Aug 2020 16:57:46
User entered 'No (N)'	System	05 Aug 2020 16:57:46

FDA-CBER-2022-1614-1750363

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '646c7717-6da6-450e-8392-5b98858814b3'	System	05 Aug 2020 16:57:46
User entered 'No (N)'	System	05 Aug 2020 16:57:46

FDA-CBER-2022-1614-1750364

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '646c7717-6da6-450e-8392-5b98858814b3'	System	05 Aug 2020 16:57:46
User entered 'None (1)'	System	05 Aug 2020 16:57:46

FDA-CBER-2022-1614-1750365

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:42', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '646c7717-6da6-450e-8392-5b98858814b3'	System	05 Aug 2020 16:57:46
User entered '05 Aug 2020 12:57'	System	05 Aug 2020 16:57:46

FDA-CBER-2022-1614-1750366

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 12:26'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750367

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750368

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 2'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750369

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:25:47', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eaf23d4a-802f-4d0a-8700-28b455d3c15f'	System	06 Aug 2020 20:26:11
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 20:26:11

FDA-CBER-2022-1614-1750370

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:25:52', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eaf23d4a-802f-4d0a-8700-28b455d3c15f'	System	06 Aug 2020 20:26:11
User entered 'No (N)'	System	06 Aug 2020 20:26:11

FDA-CBER-2022-1614-1750371

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:01', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eaf23d4a-802f-4d0a-8700-28b455d3c15f'	System	06 Aug 2020 20:26:11
User entered 'No (N)'	System	06 Aug 2020 20:26:11

FDA-CBER-2022-1614-1750372

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:04', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eaf23d4a-802f-4d0a-8700-28b455d3c15f'	System	06 Aug 2020 20:26:11
User entered 'None (1)'	System	06 Aug 2020 20:26:11

FDA-CBER-2022-1614-1750373

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:07', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eaf23d4a-802f-4d0a-8700-28b455d3c15f'	System	06 Aug 2020 20:26:11
User entered '06 Aug 2020 16:26'	System	06 Aug 2020 20:26:11

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750375

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750376

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 3'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750377

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:11', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '658a6546-2f04-4674-9fdb-70011e0cbacb'	System	08 Aug 2020 02:14:24
User entered 'None (1)'	System	08 Aug 2020 02:14:24

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '658a6546-2f04-4674-9fdb-70011e0cbacb'	System	08 Aug 2020 02:14:24
User entered 'No (N)'	System	08 Aug 2020 02:14:24

FDA-CBER-2022-1614-1750379

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:15', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '658a6546-2f04-4674-9fdb-70011e0cbacb'	System	08 Aug 2020 02:14:24
User entered 'No (N)'	System	08 Aug 2020 02:14:24

FDA-CBER-2022-1614-1750380

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '658a6546-2f04-4674-9fdb-70011e0cbacb'	System	08 Aug 2020 02:14:24
User entered 'None (1)'	System	08 Aug 2020 02:14:24

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:20', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '658a6546-2f04-4674-9fdb-70011e0cbacb'	System	08 Aug 2020 02:14:24
User entered '07 Aug 2020 22:14'	System	08 Aug 2020 02:14:24

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750383

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750384

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 4'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750385

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:24', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ef8bbe4-4e09-412a-babb-23873eaeb363'	System	09 Aug 2020 02:43:36
User entered 'None (1)'	System	09 Aug 2020 02:43:36

FDA-CBER-2022-1614-1750386

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:26', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ef8bbe4-4e09-412a-babb-23873eaeb363'	System	09 Aug 2020 02:43:36
User entered 'No (N)'	System	09 Aug 2020 02:43:36

FDA-CBER-2022-1614-1750387

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:27', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ef8bbe4-4e09-412a-babb-23873eaeb363'	System	09 Aug 2020 02:43:36
User entered 'No (N)'	System	09 Aug 2020 02:43:36

FDA-CBER-2022-1614-1750388

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:30', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ef8bbe4-4e09-412a-babb-23873eaeb363'	System	09 Aug 2020 02:43:36
User entered 'None (1)'	System	09 Aug 2020 02:43:36

FDA-CBER-2022-1614-1750389

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:32', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ef8bbe4-4e09-412a-babb-23873eaeb363'	System	09 Aug 2020 02:43:36
User entered '08 Aug 2020 22:43'	System	09 Aug 2020 02:43:36

FDA-CBER-2022-1614-1750390

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750391

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750392

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 5'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750393

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:21', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eb069847-5a9c-48bf-8104-99d79783f8c0'	System	09 Aug 2020 17:22:30
User entered 'None (1)'	System	09 Aug 2020 17:22:30

FDA-CBER-2022-1614-1750394

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eb069847-5a9c-48bf-8104-99d79783f8c0'	System	09 Aug 2020 17:22:30
User entered 'No (N)'	System	09 Aug 2020 17:22:30

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:24', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eb069847-5a9c-48bf-8104-99d79783f8c0'	System	09 Aug 2020 17:22:30
User entered 'No (N)'	System	09 Aug 2020 17:22:30

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:26', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eb069847-5a9c-48bf-8104-99d79783f8c0'	System	09 Aug 2020 17:22:30
User entered 'None (1)'	System	09 Aug 2020 17:22:30

FDA-CBER-2022-1614-1750397

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:28', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'eb069847-5a9c-48bf-8104-99d79783f8c0'	System	09 Aug 2020 17:22:30
User entered '09 Aug 2020 13:22'	System	09 Aug 2020 17:22:30

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750399

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750400

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 6'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750401

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:02', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7bc8a5ce-83a5-4755-a14a-bb86e2dd2f1b'	System	10 Aug 2020 16:07:12
User entered 'None (1)'	System	10 Aug 2020 16:07:12

FDA-CBER-2022-1614-1750402

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:04', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7bc8a5ce-83a5-4755-a14a-bb86e2dd2f1b'	System	10 Aug 2020 16:07:12
User entered 'No (N)'	System	10 Aug 2020 16:07:12

FDA-CBER-2022-1614-1750403

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:07', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7bc8a5ce-83a5-4755-a14a-bb86e2dd2f1b'	System	10 Aug 2020 16:07:12
User entered 'No (N)'	System	10 Aug 2020 16:07:12

FDA-CBER-2022-1614-1750404

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:08', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7bc8a5ce-83a5-4755-a14a-bb86e2dd2f1b'	System	10 Aug 2020 16:07:12
User entered 'None (1)'	System	10 Aug 2020 16:07:12

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:10', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7bc8a5ce-83a5-4755-a14a-bb86e2dd2f1b'	System	10 Aug 2020 16:07:12
User entered '10 Aug 2020 12:07'	System	10 Aug 2020 16:07:12

FDA-CBER-2022-1614-1750406

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750407

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750408

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 7'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750409

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:21', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c3c11131-9ac9-4b61-bd6f-a17077351eef'	System	12 Aug 2020 00:37:30
User entered 'None (1)'	System	12 Aug 2020 00:37:30

FDA-CBER-2022-1614-1750410

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:22', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c3c11131-9ac9-4b61-bd6f-a17077351eef'	System	12 Aug 2020 00:37:30
User entered 'No (N)'	System	12 Aug 2020 00:37:30

FDA-CBER-2022-1614-1750411

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:24', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c3c11131-9ac9-4b61-bd6f-a17077351eef'	System	12 Aug 2020 00:37:30
User entered 'No (N)'	System	12 Aug 2020 00:37:30

FDA-CBER-2022-1614-1750412

US3402232

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:33

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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:26', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c3c11131-9ac9-4b61-bd6f-a17077351eef'	System	12 Aug 2020 00:37:30
User entered 'None (1)'	System	12 Aug 2020 00:37:30

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:28', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c3c11131-9ac9-4b61-bd6f-a17077351eef'	System	12 Aug 2020 00:37:30
User entered '11 Aug 2020 20:37'	System	12 Aug 2020 00:37:30

FDA-CBER-2022-1614-1750414

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750415

US3402232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750416

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750417

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:15:02', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e661eab2-6270-402b-aa5f-99957f82b1b2'	System	05 Aug 2020 13:15:35
User entered 'None (0)'	System	05 Aug 2020 13:15:35

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:15:06', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e661eab2-6270-402b-aa5f-99957f82b1b2'	System	05 Aug 2020 13:15:35
User entered 'None (0)'	System	05 Aug 2020 13:15:35

FDA-CBER-2022-1614-1750419

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:15:09', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e661eab2-6270-402b-aa5f-99957f82b1b2'	System	05 Aug 2020 13:15:35
User entered 'None (0)'	System	05 Aug 2020 13:15:35

FDA-CBER-2022-1614-1750420

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:15:11', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e661eab2-6270-402b-aa5f-99957f82b1b2'	System	05 Aug 2020 13:15:35
User entered 'None (0)'	System	05 Aug 2020 13:15:35

FDA-CBER-2022-1614-1750421

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:15:14', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e661eab2-6270-402b-aa5f-99957f82b1b2'	System	05 Aug 2020 13:15:35
User entered 'None (0)'	System	05 Aug 2020 13:15:35

FDA-CBER-2022-1614-1750422

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:15:18', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e661eab2-6270-402b-aa5f-99957f82b1b2'	System	05 Aug 2020 13:15:35
User entered 'None (0)'	System	05 Aug 2020 13:15:35

FDA-CBER-2022-1614-1750423

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:15:28', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e661eab2-6270-402b-aa5f-99957f82b1b2'	System	05 Aug 2020 13:15:35
User entered 'No (N)'	System	05 Aug 2020 13:15:35

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T09:15:31', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e661eab2-6270-402b-aa5f-99957f82b1b2'	System	05 Aug 2020 13:15:35
User entered '05 Aug 2020 09:15'	System	05 Aug 2020 13:15:35

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 09:01'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750426

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 11:31'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750427

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750428

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:47', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29fdde57-558f-4158-ab79-b7ed39950d31'	System	05 Aug 2020 16:58:08
User entered 'None (0)'	System	05 Aug 2020 16:58:08

FDA-CBER-2022-1614-1750429

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:48', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29fdde57-558f-4158-ab79-b7ed39950d31'	System	05 Aug 2020 16:58:08
User entered 'None (0)'	System	05 Aug 2020 16:58:08

FDA-CBER-2022-1614-1750430

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:50', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29fdde57-558f-4158-ab79-b7ed39950d31'	System	05 Aug 2020 16:58:08
User entered 'None (0)'	System	05 Aug 2020 16:58:08

FDA-CBER-2022-1614-1750431

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:52', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29fdde57-558f-4158-ab79-b7ed39950d31'	System	05 Aug 2020 16:58:08
User entered 'None (0)'	System	05 Aug 2020 16:58:08

FDA-CBER-2022-1614-1750432

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:54', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29fdde57-558f-4158-ab79-b7ed39950d31'	System	05 Aug 2020 16:58:08
User entered 'None (0)'	System	05 Aug 2020 16:58:08

FDA-CBER-2022-1614-1750433

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:56', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29fdde57-558f-4158-ab79-b7ed39950d31'	System	05 Aug 2020 16:58:08
User entered 'None (0)'	System	05 Aug 2020 16:58:08

FDA-CBER-2022-1614-1750434

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:57:58', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29fdde57-558f-4158-ab79-b7ed39950d31'	System	05 Aug 2020 16:58:08
User entered 'No (N)'	System	05 Aug 2020 16:58:08

FDA-CBER-2022-1614-1750435

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-05T12:58:06', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29fdde57-558f-4158-ab79-b7ed39950d31'	System	05 Aug 2020 16:58:08
User entered '05 Aug 2020 12:58'	System	05 Aug 2020 16:58:08

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Aug 2020 12:26'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750437

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750438

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 2'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750439

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:10', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9259c4a6-86cd-4804-8229-7cca60f8096b'	System	06 Aug 2020 20:26:24
User entered 'None (0)'	System	06 Aug 2020 20:26:24

FDA-CBER-2022-1614-1750440

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:11', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9259c4a6-86cd-4804-8229-7cca60f8096b'	System	06 Aug 2020 20:26:24
User entered 'None (0)'	System	06 Aug 2020 20:26:24

FDA-CBER-2022-1614-1750441

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9259c4a6-86cd-4804-8229-7cca60f8096b'	System	06 Aug 2020 20:26:24
User entered 'None (0)'	System	06 Aug 2020 20:26:24

FDA-CBER-2022-1614-1750442

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:15', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9259c4a6-86cd-4804-8229-7cca60f8096b'	System	06 Aug 2020 20:26:24
User entered 'None (0)'	System	06 Aug 2020 20:26:24

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9259c4a6-86cd-4804-8229-7cca60f8096b'	System	06 Aug 2020 20:26:24
User entered 'None (0)'	System	06 Aug 2020 20:26:24

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:18', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9259c4a6-86cd-4804-8229-7cca60f8096b'	System	06 Aug 2020 20:26:24
User entered 'None (0)'	System	06 Aug 2020 20:26:24

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:20', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9259c4a6-86cd-4804-8229-7cca60f8096b'	System	06 Aug 2020 20:26:24
User entered 'No (N)'	System	06 Aug 2020 20:26:24

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-06T16:26:22', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '9259c4a6-86cd-4804-8229-7cca60f8096b'	System	06 Aug 2020 20:26:24
User entered '06 Aug 2020 16:26'	System	06 Aug 2020 20:26:24

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750448

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750449

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 3'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750450

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0d22c39e-e6d1-4139-9a4b-da20ff1b3e14'	System	08 Aug 2020 02:14:36
User entered 'None (0)'	System	08 Aug 2020 02:14:36

FDA-CBER-2022-1614-1750451

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:24', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0d22c39e-e6d1-4139-9a4b-da20ff1b3e14'	System	08 Aug 2020 02:14:36
User entered 'None (0)'	System	08 Aug 2020 02:14:36

FDA-CBER-2022-1614-1750452

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:25', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0d22c39e-e6d1-4139-9a4b-da20ff1b3e14'	System	08 Aug 2020 02:14:36
User entered 'None (0)'	System	08 Aug 2020 02:14:36

FDA-CBER-2022-1614-1750453

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:26', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0d22c39e-e6d1-4139-9a4b-da20ff1b3e14'	System	08 Aug 2020 02:14:36
User entered 'None (0)'	System	08 Aug 2020 02:14:36

FDA-CBER-2022-1614-1750454

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:27', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0d22c39e-e6d1-4139-9a4b-da20ff1b3e14'	System	08 Aug 2020 02:14:36
User entered 'None (0)'	System	08 Aug 2020 02:14:36

FDA-CBER-2022-1614-1750455

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:28', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0d22c39e-e6d1-4139-9a4b-da20ff1b3e14'	System	08 Aug 2020 02:14:36
User entered 'None (0)'	System	08 Aug 2020 02:14:36

FDA-CBER-2022-1614-1750456

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:30', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0d22c39e-e6d1-4139-9a4b-da20ff1b3e14'	System	08 Aug 2020 02:14:36
User entered 'No (N)'	System	08 Aug 2020 02:14:36

FDA-CBER-2022-1614-1750457

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-07T22:14:31', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0d22c39e-e6d1-4139-9a4b-da20ff1b3e14'	System	08 Aug 2020 02:14:36
User entered '07 Aug 2020 22:14'	System	08 Aug 2020 02:14:36

FDA-CBER-2022-1614-1750458

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750459

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750460

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 4'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750461

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:35', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c08042ea-6eca-4c71-a5be-ba17a29bad39'	System	09 Aug 2020 02:43:49
User entered 'None (0)'	System	09 Aug 2020 02:43:49

FDA-CBER-2022-1614-1750462

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:38', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c08042ea-6eca-4c71-a5be-ba17a29bad39'	System	09 Aug 2020 02:43:49
User entered 'None (0)'	System	09 Aug 2020 02:43:49

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c08042ea-6eca-4c71-a5be-ba17a29bad39'	System	09 Aug 2020 02:43:49
User entered 'None (0)'	System	09 Aug 2020 02:43:49

FDA-CBER-2022-1614-1750464

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:40', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c08042ea-6eca-4c71-a5be-ba17a29bad39'	System	09 Aug 2020 02:43:49
User entered 'None (0)'	System	09 Aug 2020 02:43:49

FDA-CBER-2022-1614-1750465

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:41', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c08042ea-6eca-4c71-a5be-ba17a29bad39'	System	09 Aug 2020 02:43:49
User entered 'None (0)'	System	09 Aug 2020 02:43:49

FDA-CBER-2022-1614-1750466

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:43', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c08042ea-6eca-4c71-a5be-ba17a29bad39'	System	09 Aug 2020 02:43:49
User entered 'None (0)'	System	09 Aug 2020 02:43:49

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:45', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c08042ea-6eca-4c71-a5be-ba17a29bad39'	System	09 Aug 2020 02:43:49
User entered 'No (N)'	System	09 Aug 2020 02:43:49

FDA-CBER-2022-1614-1750468

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-08T22:43:47', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c08042ea-6eca-4c71-a5be-ba17a29bad39'	System	09 Aug 2020 02:43:49
User entered '08 Aug 2020 22:43'	System	09 Aug 2020 02:43:49

FDA-CBER-2022-1614-1750469

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750470

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750471

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 5'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750472

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:31', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e8403916-14e9-4848-8a36-c8206ad8be9d'	System	09 Aug 2020 17:22:43
User entered 'None (0)'	System	09 Aug 2020 17:22:43

FDA-CBER-2022-1614-1750473

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:32', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e8403916-14e9-4848-8a36-c8206ad8be9d'	System	09 Aug 2020 17:22:43
User entered 'None (0)'	System	09 Aug 2020 17:22:43

FDA-CBER-2022-1614-1750474

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e8403916-14e9-4848-8a36-c8206ad8be9d'	System	09 Aug 2020 17:22:43
User entered 'None (0)'	System	09 Aug 2020 17:22:43

FDA-CBER-2022-1614-1750475

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:35', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e8403916-14e9-4848-8a36-c8206ad8be9d'	System	09 Aug 2020 17:22:43
User entered 'None (0)'	System	09 Aug 2020 17:22:43

FDA-CBER-2022-1614-1750476

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e8403916-14e9-4848-8a36-c8206ad8be9d'	System	09 Aug 2020 17:22:43
User entered 'None (0)'	System	09 Aug 2020 17:22:43

FDA-CBER-2022-1614-1750477

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:38', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e8403916-14e9-4848-8a36-c8206ad8be9d'	System	09 Aug 2020 17:22:43
User entered 'None (0)'	System	09 Aug 2020 17:22:43

FDA-CBER-2022-1614-1750478

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e8403916-14e9-4848-8a36-c8206ad8be9d'	System	09 Aug 2020 17:22:43
User entered 'No (N)'	System	09 Aug 2020 17:22:43

FDA-CBER-2022-1614-1750479

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-09T13:22:41', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e8403916-14e9-4848-8a36-c8206ad8be9d'	System	09 Aug 2020 17:22:43
User entered '09 Aug 2020 13:22'	System	09 Aug 2020 17:22:43

FDA-CBER-2022-1614-1750480

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750481

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750482

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 6'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750483

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8d6ec978-eea2-4ec5-8844-ac4b2e9e2471'	System	10 Aug 2020 16:07:30
User entered 'None (0)'	System	10 Aug 2020 16:07:30

FDA-CBER-2022-1614-1750484

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:26', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8d6ec978-eea2-4ec5-8844-ac4b2e9e2471'	System	10 Aug 2020 16:07:30
User entered 'None (0)'	System	10 Aug 2020 16:07:30

FDA-CBER-2022-1614-1750485

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:16', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8d6ec978-eea2-4ec5-8844-ac4b2e9e2471'	System	10 Aug 2020 16:07:30
User entered 'None (0)'	System	10 Aug 2020 16:07:30

FDA-CBER-2022-1614-1750486

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:18', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8d6ec978-eea2-4ec5-8844-ac4b2e9e2471'	System	10 Aug 2020 16:07:30
User entered 'None (0)'	System	10 Aug 2020 16:07:30

FDA-CBER-2022-1614-1750487

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:19', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8d6ec978-eea2-4ec5-8844-ac4b2e9e2471'	System	10 Aug 2020 16:07:30
User entered 'None (0)'	System	10 Aug 2020 16:07:30

FDA-CBER-2022-1614-1750488

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:21', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8d6ec978-eea2-4ec5-8844-ac4b2e9e2471'	System	10 Aug 2020 16:07:30
User entered 'None (0)'	System	10 Aug 2020 16:07:30

FDA-CBER-2022-1614-1750489

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8d6ec978-eea2-4ec5-8844-ac4b2e9e2471'	System	10 Aug 2020 16:07:30
User entered 'No (N)'	System	10 Aug 2020 16:07:30

FDA-CBER-2022-1614-1750490

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-10T12:07:28', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8d6ec978-eea2-4ec5-8844-ac4b2e9e2471'	System	10 Aug 2020 16:07:30
User entered '10 Aug 2020 12:07'	System	10 Aug 2020 16:07:30

FDA-CBER-2022-1614-1750491

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750492

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750493

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 7'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750494

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:30', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7b20f7e6-3329-4dd9-86bb-46ca977cfe6c'	System	12 Aug 2020 00:37:46
User entered 'None (0)'	System	12 Aug 2020 00:37:46

FDA-CBER-2022-1614-1750495

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:32', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7b20f7e6-3329-4dd9-86bb-46ca977cfe6c'	System	12 Aug 2020 00:37:46
User entered 'None (0)'	System	12 Aug 2020 00:37:46

FDA-CBER-2022-1614-1750496

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:35', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7b20f7e6-3329-4dd9-86bb-46ca977cfe6c'	System	12 Aug 2020 00:37:46
User entered 'None (0)'	System	12 Aug 2020 00:37:46

FDA-CBER-2022-1614-1750497

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7b20f7e6-3329-4dd9-86bb-46ca977cfe6c'	System	12 Aug 2020 00:37:46
User entered 'None (0)'	System	12 Aug 2020 00:37:46

FDA-CBER-2022-1614-1750498

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:38', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7b20f7e6-3329-4dd9-86bb-46ca977cfe6c'	System	12 Aug 2020 00:37:46
User entered 'None (0)'	System	12 Aug 2020 00:37:46

FDA-CBER-2022-1614-1750499

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7b20f7e6-3329-4dd9-86bb-46ca977cfe6c'	System	12 Aug 2020 00:37:46
User entered 'None (0)'	System	12 Aug 2020 00:37:46

FDA-CBER-2022-1614-1750500

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:41', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7b20f7e6-3329-4dd9-86bb-46ca977cfe6c'	System	12 Aug 2020 00:37:46
User entered 'No (N)'	System	12 Aug 2020 00:37:46

FDA-CBER-2022-1614-1750501

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-08-11T20:37:43', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '7b20f7e6-3329-4dd9-86bb-46ca977cfe6c'	System	12 Aug 2020 00:37:46
User entered '11 Aug 2020 20:37'	System	12 Aug 2020 00:37:46

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750503

US3402232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750504

US3402232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Aug 2020 11:46:45

FDA-CBER-2022-1614-1750505

US3402232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '13 Aug 2020'	Traci Hull (b) (4) (b) (4)	14 Aug 2020 11:46:45

FDA-CBER-2022-1614-1750506

US3402232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	14 Aug 2020 11:46:45

FDA-CBER-2022-1614-1750507

US3402232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Aug 2020 11:46:45

US3402232
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Aug 2020 11:46:52

FDA-CBER-2022-1614-1750509

US3402232
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	14 Aug 2020 11:46:52

FDA-CBER-2022-1614-1750510

US3402232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	21 Aug 2020 18:50:05

FDA-CBER-2022-1614-1750511

US3402232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '20 Aug 2020'	Traci Hull (b) (4) (b) (4)	21 Aug 2020 18:50:05

FDA-CBER-2022-1614-1750512

US3402232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	21 Aug 2020 18:50:05

US3402232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	21 Aug 2020 18:50:05

US3402232
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	21 Aug 2020 18:50:12

FDA-CBER-2022-1614-1750515

US3402232
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	21 Aug 2020 18:50:12

FDA-CBER-2022-1614-1750516

US3402232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Aug 2020 11:38:03

FDA-CBER-2022-1614-1750517

US3402232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	27 Aug 2020 11:38:03

FDA-CBER-2022-1614-1750518

US3402232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	27 Aug 2020 11:38:03

US3402232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Aug 2020 11:38:03

FDA-CBER-2022-1614-1750520

US3402232
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Aug 2020 11:38:08

US3402232
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	27 Aug 2020 11:38:08

FDA-CBER-2022-1614-1750522

US3402232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:08

FDA-CBER-2022-1614-1750523

US3402232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '2 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:08

FDA-CBER-2022-1614-1750524

US3402232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
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 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:08

FDA-CBER-2022-1614-1750525

US3402232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'VISIT2'	System	02 Sep 2020 12:45:08

FDA-CBER-2022-1614-1750526

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750527

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750528

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '2 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750529

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '07:52'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750530

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '2 Sep 2020 07:52'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750531

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '98.2' F	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750532

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750533

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750534

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '52'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750535

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'bpm'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750536

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '14'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750537

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'breaths/min'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750538

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '116'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750539

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750540

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '75'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750541

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750542

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750543

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750544

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '2 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750545

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:59'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750546

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '2 Sep 2020 08:59'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750547

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '98.2' F	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750548

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750549

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750550

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '59'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750551

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'bpm'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750552

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '14'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750553

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'breaths/min'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750554

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '114'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750555

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750556

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '77'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750557

US3402232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	03 Sep 2020 12:29:32

FDA-CBER-2022-1614-1750558

US3402232
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:39

FDA-CBER-2022-1614-1750559

US3402232
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '2 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:29:39

FDA-CBER-2022-1614-1750560

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750561

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750562

US3402232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:33

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 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:28

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750564

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '2 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750565

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:25'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750566

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '2 Sep 2020 08:25'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750567

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750568

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'ONCE'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750569

US3402232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:24:33
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750570

US3402232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:03

FDA-CBER-2022-1614-1750571

US3402232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '2 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:03

FDA-CBER-2022-1614-1750572

US3402232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:05'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:03

FDA-CBER-2022-1614-1750573

US3402232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '2 Sep 2020 08:05'	System	03 Sep 2020 12:30:03

FDA-CBER-2022-1614-1750574

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '2 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750575

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:24:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750576

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750577

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '08:04'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750578

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '2 Sep 2020 08:04'	System	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750579

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:24:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750580

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750581

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750582

US3402232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered empty.	System	03 Sep 2020 12:30:19

FDA-CBER-2022-1614-1750583

US3402232
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Sep 2020 12:30:22

FDA-CBER-2022-1614-1750584

US3402232
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	03 Sep 2020 12:30:22

FDA-CBER-2022-1614-1750585

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750586

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:16', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a1fa744d-545c-4c56-a342-98bad8e1fa54'	System	02 Sep 2020 13:00:32
User entered 'Yes (Y)'	System	02 Sep 2020 13:00:32

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:20', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a1fa744d-545c-4c56-a342-98bad8e1fa54'	System	02 Sep 2020 13:00:32
User entered '98.2'	System	02 Sep 2020 13:00:32

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a1fa744d-545c-4c56-a342-98bad8e1fa54'	System	02 Sep 2020 13:00:32
User entered 'No (N)'	System	02 Sep 2020 13:00:32

FDA-CBER-2022-1614-1750589

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:28', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a1fa744d-545c-4c56-a342-98bad8e1fa54'	System	02 Sep 2020 13:00:32
User entered '02 Sep 2020 09:00'	System	02 Sep 2020 13:00:32

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 08:45'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750591

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 11:15'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750592

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750593

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:05', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '50b6d434-0b13-4ab4-8527-15b58ea48d23'	System	02 Sep 2020 17:41:55
User entered 'Yes (Y)'	System	02 Sep 2020 17:41:55

FDA-CBER-2022-1614-1750594

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:11', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '50b6d434-0b13-4ab4-8527-15b58ea48d23'	System	02 Sep 2020 17:41:55
User entered '98.1'	System	02 Sep 2020 17:41:55

FDA-CBER-2022-1614-1750595

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '50b6d434-0b13-4ab4-8527-15b58ea48d23'	System	02 Sep 2020 17:41:55
User entered 'No (N)'	System	02 Sep 2020 17:41:55

FDA-CBER-2022-1614-1750596

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:16', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '50b6d434-0b13-4ab4-8527-15b58ea48d23'	System	02 Sep 2020 17:41:55
User entered '02 Sep 2020 13:41'	System	02 Sep 2020 17:41:55

FDA-CBER-2022-1614-1750597

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 12:10'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750598

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750599

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 2'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750600

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:02:27', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '654d914c-6b18-4a9b-9a1f-9032df475597'	System	03 Sep 2020 16:04:39
User entered 'Yes (Y)'	System	03 Sep 2020 16:04:39

FDA-CBER-2022-1614-1750601

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:02:31', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '654d914c-6b18-4a9b-9a1f-9032df475597'	System	03 Sep 2020 16:04:39
User entered '98.0'	System	03 Sep 2020 16:04:39

FDA-CBER-2022-1614-1750602

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:02:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '654d914c-6b18-4a9b-9a1f-9032df475597'	System	03 Sep 2020 16:04:39
User entered 'No (N)'	System	03 Sep 2020 16:04:39

FDA-CBER-2022-1614-1750603

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:02:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '654d914c-6b18-4a9b-9a1f-9032df475597'	System	03 Sep 2020 16:04:39
User entered '03 Sep 2020 12:02'	System	03 Sep 2020 16:04:39

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750605

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750606

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 3'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750607

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:14', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'af9c24e6-e069-444d-865c-4a7136a5593e'	System	05 Sep 2020 03:03:50
User entered 'Yes (Y)'	System	05 Sep 2020 03:03:50

FDA-CBER-2022-1614-1750608

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:18', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'af9c24e6-e069-444d-865c-4a7136a5593e'	System	05 Sep 2020 03:03:50
User entered '98.2'	System	05 Sep 2020 03:03:50

FDA-CBER-2022-1614-1750609

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:21', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'af9c24e6-e069-444d-865c-4a7136a5593e'	System	05 Sep 2020 03:03:50
User entered 'No (N)'	System	05 Sep 2020 03:03:50

FDA-CBER-2022-1614-1750610

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:25', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'af9c24e6-e069-444d-865c-4a7136a5593e'	System	05 Sep 2020 03:03:50
User entered '04 Sep 2020 23:02'	System	05 Sep 2020 03:03:50

FDA-CBER-2022-1614-1750611

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750612

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750613

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 4'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750614

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:07:55', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c6baed05-4398-4057-8d00-d731b3c580d1'	System	06 Sep 2020 10:08:07
User entered 'Yes (Y)'	System	06 Sep 2020 10:08:07

FDA-CBER-2022-1614-1750615

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:02', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c6baed05-4398-4057-8d00-d731b3c580d1'	System	06 Sep 2020 10:08:07
User entered '98.6'	System	06 Sep 2020 10:08:07

FDA-CBER-2022-1614-1750616

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:04', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c6baed05-4398-4057-8d00-d731b3c580d1'	System	06 Sep 2020 10:08:07
User entered 'No (N)'	System	06 Sep 2020 10:08:07

FDA-CBER-2022-1614-1750617

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:06', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c6baed05-4398-4057-8d00-d731b3c580d1'	System	06 Sep 2020 10:08:07
User entered '06 Sep 2020 06:08'	System	06 Sep 2020 10:08:07

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750619

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750620

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 5'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750621

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:10:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f7677475-031d-4af9-a90b-d610e1e8f672'	System	06 Sep 2020 16:10:46
User entered 'Yes (Y)'	System	06 Sep 2020 16:10:46

FDA-CBER-2022-1614-1750622

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:10:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f7677475-031d-4af9-a90b-d610e1e8f672'	System	06 Sep 2020 16:10:46
User entered '98.1'	System	06 Sep 2020 16:10:46

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:10:41', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f7677475-031d-4af9-a90b-d610e1e8f672'	System	06 Sep 2020 16:10:46
User entered 'No (N)'	System	06 Sep 2020 16:10:46

FDA-CBER-2022-1614-1750624

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:10:43', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f7677475-031d-4af9-a90b-d610e1e8f672'	System	06 Sep 2020 16:10:46
User entered '06 Sep 2020 12:10'	System	06 Sep 2020 16:10:46

FDA-CBER-2022-1614-1750625

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750626

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750627

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 6'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750628

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:54:54', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3f3e1c9f-3a56-429c-a275-01bf2685a81e'	System	08 Sep 2020 01:55:09
User entered 'Yes (Y)'	System	08 Sep 2020 01:55:09

FDA-CBER-2022-1614-1750629

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:01', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3f3e1c9f-3a56-429c-a275-01bf2685a81e'	System	08 Sep 2020 01:55:09
User entered '98.5'	System	08 Sep 2020 01:55:09

FDA-CBER-2022-1614-1750630

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:04', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3f3e1c9f-3a56-429c-a275-01bf2685a81e'	System	08 Sep 2020 01:55:09
User entered 'No (N)'	System	08 Sep 2020 01:55:09

FDA-CBER-2022-1614-1750631

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:07', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3f3e1c9f-3a56-429c-a275-01bf2685a81e'	System	08 Sep 2020 01:55:09
User entered '07 Sep 2020 21:55'	System	08 Sep 2020 01:55:09

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750633

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750634

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 7'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750635

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:51:51', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0b931fe6-53b6-4fb1-b0cb-d6874d072aed'	System	09 Sep 2020 06:52:05
User entered 'Yes (Y)'	System	09 Sep 2020 06:52:05

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:51:59', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0b931fe6-53b6-4fb1-b0cb-d6874d072aed'	System	09 Sep 2020 06:52:05
User entered '97.9'	System	09 Sep 2020 06:52:05

FDA-CBER-2022-1614-1750637

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:02', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0b931fe6-53b6-4fb1-b0cb-d6874d072aed'	System	09 Sep 2020 06:52:05
User entered 'No (N)'	System	09 Sep 2020 06:52:05

FDA-CBER-2022-1614-1750638

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:05', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '0b931fe6-53b6-4fb1-b0cb-d6874d072aed'	System	09 Sep 2020 06:52:05
User entered '09 Sep 2020 02:52'	System	09 Sep 2020 06:52:05

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750640

US3402232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750641

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750642

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '836d3811-8792-4f6d-b0f0-2a5f0c77f15c'	System	02 Sep 2020 13:00:49
User entered 'None (1)'	System	02 Sep 2020 13:00:49

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:37', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '836d3811-8792-4f6d-b0f0-2a5f0c77f15c'	System	02 Sep 2020 13:00:49
User entered 'No (N)'	System	02 Sep 2020 13:00:49

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US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '836d3811-8792-4f6d-b0f0-2a5f0c77f15c'	System	02 Sep 2020 13:00:49
User entered 'No (N)'	System	02 Sep 2020 13:00:49

FDA-CBER-2022-1614-1750645

US3402232

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:33

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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:41', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '836d3811-8792-4f6d-b0f0-2a5f0c77f15c'	System	02 Sep 2020 13:00:49
User entered 'None (1)'	System	02 Sep 2020 13:00:49

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:44', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '836d3811-8792-4f6d-b0f0-2a5f0c77f15c'	System	02 Sep 2020 13:00:49
User entered '02 Sep 2020 09:00'	System	02 Sep 2020 13:00:49

FDA-CBER-2022-1614-1750647

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 08:45'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750648

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 11:15'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750649

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750650

US3402232

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:33

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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:20', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '93efea57-76d0-4a25-bc2a-06b1a11427ed'	System	02 Sep 2020 17:41:58
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 17:41:58

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:22', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '93efea57-76d0-4a25-bc2a-06b1a11427ed'	System	02 Sep 2020 17:41:58
User entered 'No (N)'	System	02 Sep 2020 17:41:58

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:24', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '93efea57-76d0-4a25-bc2a-06b1a11427ed'	System	02 Sep 2020 17:41:58
User entered 'No (N)'	System	02 Sep 2020 17:41:58

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:26', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '93efea57-76d0-4a25-bc2a-06b1a11427ed'	System	02 Sep 2020 17:41:58
User entered 'None (1)'	System	02 Sep 2020 17:41:58

FDA-CBER-2022-1614-1750654

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:29', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '93efea57-76d0-4a25-bc2a-06b1a11427ed'	System	02 Sep 2020 17:41:58
User entered '02 Sep 2020 13:41'	System	02 Sep 2020 17:41:58

FDA-CBER-2022-1614-1750655

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 12:10'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750656

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750657

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 2'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750658

US3402232

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:33

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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:02:59', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ef0c6f7-20f3-4c3c-a14e-d05d1585a731'	System	03 Sep 2020 16:05:48
User entered 'Any use of prescription pain reliever or prevents daily activity (4)'	System	03 Sep 2020 16:05:48

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:01', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ef0c6f7-20f3-4c3c-a14e-d05d1585a731'	System	03 Sep 2020 16:05:48
User entered 'No (N)'	System	03 Sep 2020 16:05:48

FDA-CBER-2022-1614-1750660

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:08', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ef0c6f7-20f3-4c3c-a14e-d05d1585a731'	System	03 Sep 2020 16:05:48
User entered 'Yes (Y)'	System	03 Sep 2020 16:05:48

FDA-CBER-2022-1614-1750661

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:28', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ef0c6f7-20f3-4c3c-a14e-d05d1585a731'	System	03 Sep 2020 16:05:48
User entered '1'	System	03 Sep 2020 16:05:48

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:31', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ef0c6f7-20f3-4c3c-a14e-d05d1585a731'	System	03 Sep 2020 16:05:48
User entered 'None (1)'	System	03 Sep 2020 16:05:48

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:35', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ef0c6f7-20f3-4c3c-a14e-d05d1585a731'	System	03 Sep 2020 16:05:48
User entered '03 Sep 2020 12:03'	System	03 Sep 2020 16:05:48

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750665

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750666

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 3'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750667

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:32', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '277668dc-6ce5-40fe-88d4-c1439266d8d9'	System	05 Sep 2020 03:04:00
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 03:04:00

FDA-CBER-2022-1614-1750668

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:34', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '277668dc-6ce5-40fe-88d4-c1439266d8d9'	System	05 Sep 2020 03:04:00
User entered 'No (N)'	System	05 Sep 2020 03:04:00

FDA-CBER-2022-1614-1750669

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '277668dc-6ce5-40fe-88d4-c1439266d8d9'	System	05 Sep 2020 03:04:00
User entered 'No (N)'	System	05 Sep 2020 03:04:00

FDA-CBER-2022-1614-1750670

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:38', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '277668dc-6ce5-40fe-88d4-c1439266d8d9'	System	05 Sep 2020 03:04:00
User entered 'None (1)'	System	05 Sep 2020 03:04:00

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:40', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '277668dc-6ce5-40fe-88d4-c1439266d8d9'	System	05 Sep 2020 03:04:00
User entered '04 Sep 2020 23:02'	System	05 Sep 2020 03:04:00

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750673

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750674

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 4'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750675

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:10', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '5484719b-c4b5-4b43-9593-d73601a369d2'	System	06 Sep 2020 10:08:23
User entered 'None (1)'	System	06 Sep 2020 10:08:23

FDA-CBER-2022-1614-1750676

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '5484719b-c4b5-4b43-9593-d73601a369d2'	System	06 Sep 2020 10:08:23
User entered 'No (N)'	System	06 Sep 2020 10:08:23

FDA-CBER-2022-1614-1750677

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:15', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '5484719b-c4b5-4b43-9593-d73601a369d2'	System	06 Sep 2020 10:08:23
User entered 'No (N)'	System	06 Sep 2020 10:08:23

FDA-CBER-2022-1614-1750678

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '5484719b-c4b5-4b43-9593-d73601a369d2'	System	06 Sep 2020 10:08:23
User entered 'None (1)'	System	06 Sep 2020 10:08:23

FDA-CBER-2022-1614-1750679

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:20', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '5484719b-c4b5-4b43-9593-d73601a369d2'	System	06 Sep 2020 10:08:23
User entered '06 Sep 2020 06:08'	System	06 Sep 2020 10:08:23

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750681

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750682

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 5'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750683

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:10:52', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c45714d8-4537-45bb-b9b6-a723ad203268'	System	06 Sep 2020 16:11:05
User entered 'None (1)'	System	06 Sep 2020 16:11:05

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:10:55', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c45714d8-4537-45bb-b9b6-a723ad203268'	System	06 Sep 2020 16:11:05
User entered 'No (N)'	System	06 Sep 2020 16:11:05

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US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:10:58', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c45714d8-4537-45bb-b9b6-a723ad203268'	System	06 Sep 2020 16:11:05
User entered 'No (N)'	System	06 Sep 2020 16:11:05

FDA-CBER-2022-1614-1750686

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c45714d8-4537-45bb-b9b6-a723ad203268'	System	06 Sep 2020 16:11:05
User entered 'None (1)'	System	06 Sep 2020 16:11:05

FDA-CBER-2022-1614-1750687

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:02', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c45714d8-4537-45bb-b9b6-a723ad203268'	System	06 Sep 2020 16:11:05
User entered '06 Sep 2020 12:11'	System	06 Sep 2020 16:11:05

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750689

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750690

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 6'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750691

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:10', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f3512632-d859-4ea0-a6ae-22e75b970227'	System	08 Sep 2020 01:55:23
User entered 'None (1)'	System	08 Sep 2020 01:55:23

FDA-CBER-2022-1614-1750692

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f3512632-d859-4ea0-a6ae-22e75b970227'	System	08 Sep 2020 01:55:23
User entered 'No (N)'	System	08 Sep 2020 01:55:23

FDA-CBER-2022-1614-1750693

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:14', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f3512632-d859-4ea0-a6ae-22e75b970227'	System	08 Sep 2020 01:55:23
User entered 'No (N)'	System	08 Sep 2020 01:55:23

FDA-CBER-2022-1614-1750694

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:16', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f3512632-d859-4ea0-a6ae-22e75b970227'	System	08 Sep 2020 01:55:23
User entered 'None (1)'	System	08 Sep 2020 01:55:23

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:20', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'f3512632-d859-4ea0-a6ae-22e75b970227'	System	08 Sep 2020 01:55:23
User entered '07 Sep 2020 21:55'	System	08 Sep 2020 01:55:23

FDA-CBER-2022-1614-1750696

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750697

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750698

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 7'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750699

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:09', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'db680876-cc39-4ef3-8ff1-c4d814feaaa8'	System	09 Sep 2020 06:52:19
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750700

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:11', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'db680876-cc39-4ef3-8ff1-c4d814feaaa8'	System	09 Sep 2020 06:52:19
User entered 'No (N)'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750701

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'db680876-cc39-4ef3-8ff1-c4d814feaaa8'	System	09 Sep 2020 06:52:19
User entered 'No (N)'	System	09 Sep 2020 06:52:19

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:14', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'db680876-cc39-4ef3-8ff1-c4d814feaaa8'	System	09 Sep 2020 06:52:19
User entered 'None (1)'	System	09 Sep 2020 06:52:19

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'db680876-cc39-4ef3-8ff1-c4d814feaaa8'	System	09 Sep 2020 06:52:19
User entered '09 Sep 2020 02:52'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750704

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750705

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750706

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750707

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:50', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8501255d-e0bd-45f9-811e-5f3cb78d5a69'	System	02 Sep 2020 13:01:06
User entered 'None (0)'	System	02 Sep 2020 13:01:06

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:52', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8501255d-e0bd-45f9-811e-5f3cb78d5a69'	System	02 Sep 2020 13:01:06
User entered 'None (0)'	System	02 Sep 2020 13:01:06

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:53', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8501255d-e0bd-45f9-811e-5f3cb78d5a69'	System	02 Sep 2020 13:01:06
User entered 'None (0)'	System	02 Sep 2020 13:01:06

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:54', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8501255d-e0bd-45f9-811e-5f3cb78d5a69'	System	02 Sep 2020 13:01:06
User entered 'None (0)'	System	02 Sep 2020 13:01:06

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:56', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8501255d-e0bd-45f9-811e-5f3cb78d5a69'	System	02 Sep 2020 13:01:06
User entered 'None (0)'	System	02 Sep 2020 13:01:06

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:57', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8501255d-e0bd-45f9-811e-5f3cb78d5a69'	System	02 Sep 2020 13:01:06
User entered 'None (0)'	System	02 Sep 2020 13:01:06

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:00:59', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8501255d-e0bd-45f9-811e-5f3cb78d5a69'	System	02 Sep 2020 13:01:06
User entered 'No (N)'	System	02 Sep 2020 13:01:06

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T09:01:01', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8501255d-e0bd-45f9-811e-5f3cb78d5a69'	System	02 Sep 2020 13:01:06
User entered '02 Sep 2020 09:01'	System	02 Sep 2020 13:01:06

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 08:45'	System	02 Sep 2020 12:45:28

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US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 11:15'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750717

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750718

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:32', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '72c6b5fb-e6eb-455a-970d-974c7a4de3b7'	System	02 Sep 2020 17:42:02
User entered 'None (0)'	System	02 Sep 2020 17:42:02

FDA-CBER-2022-1614-1750719

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:34', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '72c6b5fb-e6eb-455a-970d-974c7a4de3b7'	System	02 Sep 2020 17:42:02
User entered 'None (0)'	System	02 Sep 2020 17:42:02

FDA-CBER-2022-1614-1750720

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '72c6b5fb-e6eb-455a-970d-974c7a4de3b7'	System	02 Sep 2020 17:42:02
User entered 'None (0)'	System	02 Sep 2020 17:42:02

FDA-CBER-2022-1614-1750721

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:37', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '72c6b5fb-e6eb-455a-970d-974c7a4de3b7'	System	02 Sep 2020 17:42:02
User entered 'None (0)'	System	02 Sep 2020 17:42:02

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:38', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '72c6b5fb-e6eb-455a-970d-974c7a4de3b7'	System	02 Sep 2020 17:42:02
User entered 'None (0)'	System	02 Sep 2020 17:42:02

FDA-CBER-2022-1614-1750723

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:40', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '72c6b5fb-e6eb-455a-970d-974c7a4de3b7'	System	02 Sep 2020 17:42:02
User entered 'None (0)'	System	02 Sep 2020 17:42:02

FDA-CBER-2022-1614-1750724

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:42', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '72c6b5fb-e6eb-455a-970d-974c7a4de3b7'	System	02 Sep 2020 17:42:02
User entered 'No (N)'	System	02 Sep 2020 17:42:02

FDA-CBER-2022-1614-1750725

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-02T13:41:45', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '72c6b5fb-e6eb-455a-970d-974c7a4de3b7'	System	02 Sep 2020 17:42:02
User entered '02 Sep 2020 13:41'	System	02 Sep 2020 17:42:02

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '02 Sep 2020 12:10'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750727

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750728

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 2'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750729

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8bfd34e6-79c4-4168-b251-1f28b50df578'	System	03 Sep 2020 16:06:17
User entered 'None (0)'	System	03 Sep 2020 16:06:17

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:42', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8bfd34e6-79c4-4168-b251-1f28b50df578'	System	03 Sep 2020 16:06:17
User entered 'None (0)'	System	03 Sep 2020 16:06:17

FDA-CBER-2022-1614-1750731

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:44', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8bfd34e6-79c4-4168-b251-1f28b50df578'	System	03 Sep 2020 16:06:17
User entered 'None (0)'	System	03 Sep 2020 16:06:17

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:45', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8bfd34e6-79c4-4168-b251-1f28b50df578'	System	03 Sep 2020 16:06:17
User entered 'None (0)'	System	03 Sep 2020 16:06:17

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:47', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8bfd34e6-79c4-4168-b251-1f28b50df578'	System	03 Sep 2020 16:06:17
User entered 'None (0)'	System	03 Sep 2020 16:06:17

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:48', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8bfd34e6-79c4-4168-b251-1f28b50df578'	System	03 Sep 2020 16:06:17
User entered 'None (0)'	System	03 Sep 2020 16:06:17

FDA-CBER-2022-1614-1750735

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:54', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8bfd34e6-79c4-4168-b251-1f28b50df578'	System	03 Sep 2020 16:06:17
User entered 'No (N)'	System	03 Sep 2020 16:06:17

FDA-CBER-2022-1614-1750736

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-03T12:03:57', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '8bfd34e6-79c4-4168-b251-1f28b50df578'	System	03 Sep 2020 16:06:17
User entered '03 Sep 2020 12:03'	System	03 Sep 2020 16:06:17

FDA-CBER-2022-1614-1750737

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750738

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750739

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 3'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750740

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:44', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '085e40fd-9151-4d58-96f9-cb97bc55d6d2'	System	05 Sep 2020 03:04:30
User entered 'None (0)'	System	05 Sep 2020 03:04:30

FDA-CBER-2022-1614-1750741

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:45', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '085e40fd-9151-4d58-96f9-cb97bc55d6d2'	System	05 Sep 2020 03:04:30
User entered 'None (0)'	System	05 Sep 2020 03:04:30

FDA-CBER-2022-1614-1750742

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:46', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '085e40fd-9151-4d58-96f9-cb97bc55d6d2'	System	05 Sep 2020 03:04:30
User entered 'None (0)'	System	05 Sep 2020 03:04:30

FDA-CBER-2022-1614-1750743

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:47', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '085e40fd-9151-4d58-96f9-cb97bc55d6d2'	System	05 Sep 2020 03:04:30
User entered 'None (0)'	System	05 Sep 2020 03:04:30

FDA-CBER-2022-1614-1750744

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:49', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '085e40fd-9151-4d58-96f9-cb97bc55d6d2'	System	05 Sep 2020 03:04:30
User entered 'None (0)'	System	05 Sep 2020 03:04:30

FDA-CBER-2022-1614-1750745

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:02:51', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '085e40fd-9151-4d58-96f9-cb97bc55d6d2'	System	05 Sep 2020 03:04:30
User entered 'None (0)'	System	05 Sep 2020 03:04:30

FDA-CBER-2022-1614-1750746

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:03:07', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '085e40fd-9151-4d58-96f9-cb97bc55d6d2'	System	05 Sep 2020 03:04:30
User entered 'No (N)'	System	05 Sep 2020 03:04:30

FDA-CBER-2022-1614-1750747

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-04T23:03:09', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '085e40fd-9151-4d58-96f9-cb97bc55d6d2'	System	05 Sep 2020 03:04:30
User entered '04 Sep 2020 23:03'	System	05 Sep 2020 03:04:30

FDA-CBER-2022-1614-1750748

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750749

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750750

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 4'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750751

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '26b07c0b-ca41-4f78-8ad7-da1a08a3ff2c'	System	06 Sep 2020 10:08:39
User entered 'None (0)'	System	06 Sep 2020 10:08:39

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:24', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '26b07c0b-ca41-4f78-8ad7-da1a08a3ff2c'	System	06 Sep 2020 10:08:39
User entered 'None (0)'	System	06 Sep 2020 10:08:39

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:25', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '26b07c0b-ca41-4f78-8ad7-da1a08a3ff2c'	System	06 Sep 2020 10:08:39
User entered 'None (0)'	System	06 Sep 2020 10:08:39

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:27', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '26b07c0b-ca41-4f78-8ad7-da1a08a3ff2c'	System	06 Sep 2020 10:08:39
User entered 'None (0)'	System	06 Sep 2020 10:08:39

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:29', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '26b07c0b-ca41-4f78-8ad7-da1a08a3ff2c'	System	06 Sep 2020 10:08:39
User entered 'None (0)'	System	06 Sep 2020 10:08:39

FDA-CBER-2022-1614-1750756

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:31', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '26b07c0b-ca41-4f78-8ad7-da1a08a3ff2c'	System	06 Sep 2020 10:08:39
User entered 'None (0)'	System	06 Sep 2020 10:08:39

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '26b07c0b-ca41-4f78-8ad7-da1a08a3ff2c'	System	06 Sep 2020 10:08:39
User entered 'No (N)'	System	06 Sep 2020 10:08:39

FDA-CBER-2022-1614-1750758

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T06:08:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '26b07c0b-ca41-4f78-8ad7-da1a08a3ff2c'	System	06 Sep 2020 10:08:39
User entered '06 Sep 2020 06:08'	System	06 Sep 2020 10:08:39

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750760

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750761

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 5'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750762

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:09', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '14727d29-a810-47e8-8c5c-3aa831a0b95e'	System	06 Sep 2020 16:11:21
User entered 'None (0)'	System	06 Sep 2020 16:11:21

FDA-CBER-2022-1614-1750763

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:10', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '14727d29-a810-47e8-8c5c-3aa831a0b95e'	System	06 Sep 2020 16:11:21
User entered 'None (0)'	System	06 Sep 2020 16:11:21

FDA-CBER-2022-1614-1750764

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:11', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '14727d29-a810-47e8-8c5c-3aa831a0b95e'	System	06 Sep 2020 16:11:21
User entered 'None (0)'	System	06 Sep 2020 16:11:21

FDA-CBER-2022-1614-1750765

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '14727d29-a810-47e8-8c5c-3aa831a0b95e'	System	06 Sep 2020 16:11:21
User entered 'None (0)'	System	06 Sep 2020 16:11:21

FDA-CBER-2022-1614-1750766

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:14', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '14727d29-a810-47e8-8c5c-3aa831a0b95e'	System	06 Sep 2020 16:11:21
User entered 'None (0)'	System	06 Sep 2020 16:11:21

FDA-CBER-2022-1614-1750767

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:15', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '14727d29-a810-47e8-8c5c-3aa831a0b95e'	System	06 Sep 2020 16:11:21
User entered 'None (0)'	System	06 Sep 2020 16:11:21

FDA-CBER-2022-1614-1750768

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '14727d29-a810-47e8-8c5c-3aa831a0b95e'	System	06 Sep 2020 16:11:21
User entered 'No (N)'	System	06 Sep 2020 16:11:21

FDA-CBER-2022-1614-1750769

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-06T12:11:19', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '14727d29-a810-47e8-8c5c-3aa831a0b95e'	System	06 Sep 2020 16:11:21
User entered '06 Sep 2020 12:11'	System	06 Sep 2020 16:11:21

FDA-CBER-2022-1614-1750770

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750771

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750772

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 6'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750773

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c194ead7-1e8a-447a-9fbe-6024a3ffd38a'	System	08 Sep 2020 01:55:38
User entered 'None (0)'	System	08 Sep 2020 01:55:38

FDA-CBER-2022-1614-1750774

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:24', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c194ead7-1e8a-447a-9fbe-6024a3ffd38a'	System	08 Sep 2020 01:55:38
User entered 'None (0)'	System	08 Sep 2020 01:55:38

FDA-CBER-2022-1614-1750775

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:26', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c194ead7-1e8a-447a-9fbe-6024a3ffd38a'	System	08 Sep 2020 01:55:38
User entered 'None (0)'	System	08 Sep 2020 01:55:38

FDA-CBER-2022-1614-1750776

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:27', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c194ead7-1e8a-447a-9fbe-6024a3ffd38a'	System	08 Sep 2020 01:55:38
User entered 'None (0)'	System	08 Sep 2020 01:55:38

FDA-CBER-2022-1614-1750777

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:28', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c194ead7-1e8a-447a-9fbe-6024a3ffd38a'	System	08 Sep 2020 01:55:38
User entered 'None (0)'	System	08 Sep 2020 01:55:38

FDA-CBER-2022-1614-1750778

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:30', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c194ead7-1e8a-447a-9fbe-6024a3ffd38a'	System	08 Sep 2020 01:55:38
User entered 'None (0)'	System	08 Sep 2020 01:55:38

FDA-CBER-2022-1614-1750779

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:32', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c194ead7-1e8a-447a-9fbe-6024a3ffd38a'	System	08 Sep 2020 01:55:38
User entered 'No (N)'	System	08 Sep 2020 01:55:38

FDA-CBER-2022-1614-1750780

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-07T21:55:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c194ead7-1e8a-447a-9fbe-6024a3ffd38a'	System	08 Sep 2020 01:55:38
User entered '07 Sep 2020 21:55'	System	08 Sep 2020 01:55:38

FDA-CBER-2022-1614-1750781

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750782

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750783

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	02 Sep 2020 12:45:28
User entered 'Day 7'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750784

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a2414a97-ba5f-49d7-a29d-f66de1bd12d3'	System	09 Sep 2020 06:52:53
User entered 'None (0)'	System	09 Sep 2020 06:52:53

FDA-CBER-2022-1614-1750785

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:38', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a2414a97-ba5f-49d7-a29d-f66de1bd12d3'	System	09 Sep 2020 06:52:53
User entered 'None (0)'	System	09 Sep 2020 06:52:53

FDA-CBER-2022-1614-1750786

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:42', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a2414a97-ba5f-49d7-a29d-f66de1bd12d3'	System	09 Sep 2020 06:52:53
User entered 'None (0)'	System	09 Sep 2020 06:52:53

FDA-CBER-2022-1614-1750787

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:43', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a2414a97-ba5f-49d7-a29d-f66de1bd12d3'	System	09 Sep 2020 06:52:53
User entered 'None (0)'	System	09 Sep 2020 06:52:53

FDA-CBER-2022-1614-1750788

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:45', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a2414a97-ba5f-49d7-a29d-f66de1bd12d3'	System	09 Sep 2020 06:52:53
User entered 'None (0)'	System	09 Sep 2020 06:52:53

FDA-CBER-2022-1614-1750789

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:46', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a2414a97-ba5f-49d7-a29d-f66de1bd12d3'	System	09 Sep 2020 06:52:53
User entered 'None (0)'	System	09 Sep 2020 06:52:53

FDA-CBER-2022-1614-1750790

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:49', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a2414a97-ba5f-49d7-a29d-f66de1bd12d3'	System	09 Sep 2020 06:52:53
User entered 'No (N)'	System	09 Sep 2020 06:52:53

FDA-CBER-2022-1614-1750791

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-09-09T02:52:51', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'a2414a97-ba5f-49d7-a29d-f66de1bd12d3'	System	09 Sep 2020 06:52:53
User entered '09 Sep 2020 02:52'	System	09 Sep 2020 06:52:53

FDA-CBER-2022-1614-1750792

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750793

US3402232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 12:45:28

FDA-CBER-2022-1614-1750794

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(8)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	09 Sep 2020 06:52:19
User entered 'Day 8'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750795

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(8)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06

FDA-CBER-2022-1614-1750796

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(8)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06

FDA-CBER-2022-1614-1750797

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(8)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750798

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(8)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750799

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(9)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	09 Sep 2020 06:52:19
User entered 'Day 9'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750800

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(9)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06

FDA-CBER-2022-1614-1750801

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(9)
Generated On: 09 Jun 2021 17:24:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06

FDA-CBER-2022-1614-1750802

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(9)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750803

US3402232
Folder: Diary Dose 2 (1)
Form: Injection Pain_Day(9)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750804

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	09 Sep 2020 06:52:19
User entered 'Day 8'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750805

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06

FDA-CBER-2022-1614-1750806

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06

FDA-CBER-2022-1614-1750807

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750808

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750809

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	09 Sep 2020 06:52:19
User entered 'Day 9'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750810

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:24:33
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 04:09:06

FDA-CBER-2022-1614-1750811

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:24:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06

FDA-CBER-2022-1614-1750812

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:24:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750813

US3402232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 17:24:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 06:52:19

FDA-CBER-2022-1614-1750814

US3402232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Sep 2020 19:21:49

FDA-CBER-2022-1614-1750815

US3402232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '9 Sep 2020'	Traci Hull (b) (4) (b) (4)	09 Sep 2020 19:21:49

FDA-CBER-2022-1614-1750816

US3402232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	09 Sep 2020 19:21:49

FDA-CBER-2022-1614-1750817

US3402232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Sep 2020 19:21:49

FDA-CBER-2022-1614-1750818

US3402232
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	09 Sep 2020 19:21:37

FDA-CBER-2022-1614-1750819

US3402232
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	09 Sep 2020 19:21:37

FDA-CBER-2022-1614-1750820

US3402232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:09:10

FDA-CBER-2022-1614-1750821

US3402232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '16 Sep 2020'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:09:10

FDA-CBER-2022-1614-1750822

US3402232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:09:10

FDA-CBER-2022-1614-1750823

US3402232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:09:10

FDA-CBER-2022-1614-1750824

US3402232
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 21:09:01

FDA-CBER-2022-1614-1750825

US3402232
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	16 Sep 2020 21:09:01

FDA-CBER-2022-1614-1750826

US3402232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 20:54:34

FDA-CBER-2022-1614-1750827

US3402232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '23 Sep 2020'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 20:54:34

FDA-CBER-2022-1614-1750828

US3402232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 20:54:34

FDA-CBER-2022-1614-1750829

US3402232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Sep 2020 20:54:34

US3402232
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 20:54:38

FDA-CBER-2022-1614-1750831

US3402232
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	24 Sep 2020 20:54:38

FDA-CBER-2022-1614-1750832

US3402232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:18:32

FDA-CBER-2022-1614-1750833

US3402232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '30 Sep 2020'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:18:32

FDA-CBER-2022-1614-1750834

US3402232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
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 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:18:32

FDA-CBER-2022-1614-1750835

US3402232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'VISIT3'	System	30 Sep 2020 19:18:32

FDA-CBER-2022-1614-1750836

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750837

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '30 Sep 2020'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750838

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '14:38'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750839

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '30 Sep 2020 14:38'	System	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750840

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '36.2' C	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750841

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750842

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750843

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '60'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750844

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'bpm'	System	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750845

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '16'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750846

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'breaths/min'	System	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750847

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '118'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750848

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750849

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '64'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750850

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered 'mmHg'	System	30 Sep 2020 19:19:01

FDA-CBER-2022-1614-1750851

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57

FDA-CBER-2022-1614-1750852

US3402232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57

FDA-CBER-2022-1614-1750853

US3402232
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:17

FDA-CBER-2022-1614-1750854

US3402232
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:17

FDA-CBER-2022-1614-1750855

US3402232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:30

FDA-CBER-2022-1614-1750856

US3402232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '30 Sep 2020'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:30

FDA-CBER-2022-1614-1750857

US3402232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered '14:44'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:19:30

FDA-CBER-2022-1614-1750858

US3402232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '30 Sep 2020 14:44'	System	30 Sep 2020 19:19:30

FDA-CBER-2022-1614-1750859

US3402232
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:17:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 19:18:15

FDA-CBER-2022-1614-1750860

US3402232
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	30 Sep 2020 19:18:15

FDA-CBER-2022-1614-1750861

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 64'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750862

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-05T00:33:47', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'ceace900-87a8-4410-8ff8-d24004299280'	System	05 Oct 2020 04:34:01
User entered 'No (N)'	System	05 Oct 2020 04:34:01

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-05T00:33:51', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'ceace900-87a8-4410-8ff8-d24004299280'	System	05 Oct 2020 04:34:01
User entered 'No (N)'	System	05 Oct 2020 04:34:01

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-05T00:33:57', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'ceace900-87a8-4410-8ff8-d24004299280'	System	05 Oct 2020 04:34:01
User entered '05 Oct 2020 00:33:57'	System	05 Oct 2020 04:34:01

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750866

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750867

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 71'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750868

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-12T07:14:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '472a9d22-b3ba-4ca4-a639-28e1bd879d1a'	System	12 Oct 2020 11:14:47
User entered 'No (N)'	System	12 Oct 2020 11:14:47

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-12T07:14:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '472a9d22-b3ba-4ca4-a639-28e1bd879d1a'	System	12 Oct 2020 11:14:47
User entered 'No (N)'	System	12 Oct 2020 11:14:47

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-12T07:14:40', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '472a9d22-b3ba-4ca4-a639-28e1bd879d1a'	System	12 Oct 2020 11:14:47
User entered '12 Oct 2020 07:14:40'	System	12 Oct 2020 11:14:47

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750872

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750873

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 78'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750874

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-19T06:35:18', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'b4d7ec6e-8179-4b26-88d8-7d4071d0708f'	System	19 Oct 2020 10:35:28
User entered 'No (N)'	System	19 Oct 2020 10:35:28

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-19T06:35:22', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'b4d7ec6e-8179-4b26-88d8-7d4071d0708f'	System	19 Oct 2020 10:35:28
User entered 'No (N)'	System	19 Oct 2020 10:35:28

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-10-19T06:35:25', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'b4d7ec6e-8179-4b26-88d8-7d4071d0708f'	System	19 Oct 2020 10:35:28
User entered '19 Oct 2020 06:35:25'	System	19 Oct 2020 10:35:28

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750878

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750879

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 92'	System	05 Aug 2020 12:59:27

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750887

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750888

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750889

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750891

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750897

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750898

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 12:59:27

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 12:59:27

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 99'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750908

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-11-11T10:36:10', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '86f9fc81-b489-4d9f-8e06-d544b6631df1'	System	11 Nov 2020 15:36:23
User entered 'No (N)'	System	11 Nov 2020 15:36:23

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-11-11T10:36:15', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '86f9fc81-b489-4d9f-8e06-d544b6631df1'	System	11 Nov 2020 15:36:23
User entered 'No (N)'	System	11 Nov 2020 15:36:23

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-11-11T10:36:18', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '86f9fc81-b489-4d9f-8e06-d544b6631df1'	System	11 Nov 2020 15:36:23
User entered '11 Nov 2020 10:36:18'	System	11 Nov 2020 15:36:23

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750912

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:09:06
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 12:59:27

FDA-CBER-2022-1614-1750913

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22
Data entry locked.	System	05 Aug 2020 12:59:27
User entered 'Day 106'	System	05 Aug 2020 12:59:27

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 12:59:27

US3402232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:03:45
DataPoint activated (WR#5348247)	System	13 Apr 2021 18:12:59
DataPoint Inactivated.	System	01 Apr 2021 21:02:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:07:22
Data entry locked.	System	05 Aug 2020 12:59:27
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 12:59:27

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750942

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750947

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750948

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750949

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750950

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750951

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750952

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750953

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750954

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750955

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750956

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750957

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750958

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750959

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750960

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750961

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750962

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750963

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1750967

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750968

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750969

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750970

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-11-30T14:35:30', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'd3413ee9-5973-4b0f-91dc-96cdc39698b9'	System	30 Nov 2020 19:35:38
User entered 'No (N)'	System	30 Nov 2020 19:35:38

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-11-30T14:35:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'd3413ee9-5973-4b0f-91dc-96cdc39698b9'	System	30 Nov 2020 19:35:38
User entered 'No (N)'	System	30 Nov 2020 19:35:38

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-11-30T14:35:37', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'd3413ee9-5973-4b0f-91dc-96cdc39698b9'	System	30 Nov 2020 19:35:38
User entered '30 Nov 2020 14:35:37'	System	30 Nov 2020 19:35:38

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750974

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750975

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750976

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-04T04:09:06', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'da476abb-1600-41d3-b536-8bb11f578dfe'	System	04 Dec 2020 09:09:15
User entered 'No (N)'	System	04 Dec 2020 09:09:15

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-04T04:09:09', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'da476abb-1600-41d3-b536-8bb11f578dfe'	System	04 Dec 2020 09:09:15
User entered 'No (N)'	System	04 Dec 2020 09:09:15

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-04T04:09:12', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'da476abb-1600-41d3-b536-8bb11f578dfe'	System	04 Dec 2020 09:09:15
User entered '04 Dec 2020 04:09:12'	System	04 Dec 2020 09:09:15

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750980

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750981

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750982

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-11T05:52:13', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '839c89ce-fb2e-4fab-99bb-1efba58e1ad6'	System	11 Dec 2020 10:52:21
User entered 'No (N)'	System	11 Dec 2020 10:52:21

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-11T05:52:17', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '839c89ce-fb2e-4fab-99bb-1efba58e1ad6'	System	11 Dec 2020 10:52:21
User entered 'No (N)'	System	11 Dec 2020 10:52:21

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-11T05:52:20', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '839c89ce-fb2e-4fab-99bb-1efba58e1ad6'	System	11 Dec 2020 10:52:21
User entered '11 Dec 2020 05:52:20'	System	11 Dec 2020 10:52:21

FDA-CBER-2022-1614-1750985

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750986

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750987

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750988

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-18T03:02:41', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '967a30d4-351e-4540-840f-ecde7b8ef857'	System	18 Dec 2020 08:03:32
User entered 'No (N)'	System	18 Dec 2020 08:03:32

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-18T03:03:09', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '967a30d4-351e-4540-840f-ecde7b8ef857'	System	18 Dec 2020 08:03:32
User entered 'Yes (Y)'	System	18 Dec 2020 08:03:32

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-18T03:03:14', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '967a30d4-351e-4540-840f-ecde7b8ef857'	System	18 Dec 2020 08:03:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 08:03:32

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2020-12-18T03:03:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '967a30d4-351e-4540-840f-ecde7b8ef857'	System	18 Dec 2020 08:03:32
User entered '18 Dec 2020 03:03:23'	System	18 Dec 2020 08:03:32

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750993

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750994

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1750995

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751000

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751001

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751002

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751003

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751004

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751005

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751006

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751007

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751008

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751009

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751010

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751011

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751012

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751013

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751014

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751015

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751016

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751020

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751021

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751022

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751028

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751029

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751030

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751031

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751032

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751033

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751034

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751035

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751036

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751037

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751038

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751040

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751043

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751044

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751049

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751050

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-08T02:25:48', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ede412f-be1c-4ffc-bbac-81e61c869d5b'	System	08 Jan 2021 07:26:00
User entered 'No (N)'	System	08 Jan 2021 07:26:00

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-08T02:25:56', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ede412f-be1c-4ffc-bbac-81e61c869d5b'	System	08 Jan 2021 07:26:00
User entered 'No (N)'	System	08 Jan 2021 07:26:00

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-08T02:26:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3ede412f-be1c-4ffc-bbac-81e61c869d5b'	System	08 Jan 2021 07:26:00
User entered '08 Jan 2021 02:26:00'	System	08 Jan 2021 07:26:00

FDA-CBER-2022-1614-1751054

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751055

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751056

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751057

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-15T08:48:24', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29a8d559-791b-403a-a504-04b19b88e003'	System	15 Jan 2021 13:48:42
User entered 'No (N)'	System	15 Jan 2021 13:48:42

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-15T08:48:36', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29a8d559-791b-403a-a504-04b19b88e003'	System	15 Jan 2021 13:48:42
User entered 'No (N)'	System	15 Jan 2021 13:48:42

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-15T08:48:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '29a8d559-791b-403a-a504-04b19b88e003'	System	15 Jan 2021 13:48:42
User entered '15 Jan 2021 08:48:39'	System	15 Jan 2021 13:48:42

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751061

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751062

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751063

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-22T01:20:15', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c1a67886-78b4-4f56-90e7-b32edf45c64a'	System	22 Jan 2021 06:20:27
User entered 'No (N)'	System	22 Jan 2021 06:20:27

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-22T01:20:19', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c1a67886-78b4-4f56-90e7-b32edf45c64a'	System	22 Jan 2021 06:20:27
User entered 'No (N)'	System	22 Jan 2021 06:20:27

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-22T01:20:25', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'c1a67886-78b4-4f56-90e7-b32edf45c64a'	System	22 Jan 2021 06:20:27
User entered '22 Jan 2021 01:20:25'	System	22 Jan 2021 06:20:27

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751067

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751068

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-29T04:51:39', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3593a216-a037-4723-95d1-94df22f3bdfd'	System	29 Jan 2021 09:51:49
User entered 'No (N)'	System	29 Jan 2021 09:51:49

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-29T04:51:42', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3593a216-a037-4723-95d1-94df22f3bdfd'	System	29 Jan 2021 09:51:49
User entered 'No (N)'	System	29 Jan 2021 09:51:49

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-01-29T04:51:46', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '3593a216-a037-4723-95d1-94df22f3bdfd'	System	29 Jan 2021 09:51:49
User entered '29 Jan 2021 04:51:46'	System	29 Jan 2021 09:51:49

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751073

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751074

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751075

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-09T06:06:01', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'b4cea427-228b-48db-abb1-40da33e9284d'	System	09 Feb 2021 11:06:13
User entered 'No (N)'	System	09 Feb 2021 11:06:13

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-09T06:06:03', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'b4cea427-228b-48db-abb1-40da33e9284d'	System	09 Feb 2021 11:06:13
User entered 'No (N)'	System	09 Feb 2021 11:06:13

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-09T06:06:07', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'b4cea427-228b-48db-abb1-40da33e9284d'	System	09 Feb 2021 11:06:13
User entered '09 Feb 2021 06:06:07'	System	09 Feb 2021 11:06:13

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751079

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751080

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751081

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-12T01:04:27', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'edd3bf93-5875-41c0-856b-67ce611d074d'	System	12 Feb 2021 06:04:37
User entered 'No (N)'	System	12 Feb 2021 06:04:37

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-12T01:04:30', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'edd3bf93-5875-41c0-856b-67ce611d074d'	System	12 Feb 2021 06:04:37
User entered 'No (N)'	System	12 Feb 2021 06:04:37

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-12T01:04:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'edd3bf93-5875-41c0-856b-67ce611d074d'	System	12 Feb 2021 06:04:37
User entered '12 Feb 2021 01:04:33'	System	12 Feb 2021 06:04:37

FDA-CBER-2022-1614-1751084

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751085

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751086

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-19T04:58:23', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '852c3803-e952-4744-ac73-053cf9841eaa'	System	19 Feb 2021 09:58:48
User entered 'No (N)'	System	19 Feb 2021 09:58:48

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-19T04:58:27', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '852c3803-e952-4744-ac73-053cf9841eaa'	System	19 Feb 2021 09:58:48
User entered 'Yes (Y)'	System	19 Feb 2021 09:58:48

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-19T04:58:33', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '852c3803-e952-4744-ac73-053cf9841eaa'	System	19 Feb 2021 09:58:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Feb 2021 09:58:48

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-19T04:58:37', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '852c3803-e952-4744-ac73-053cf9841eaa'	System	19 Feb 2021 09:58:48
User entered '19 Feb 2021 04:58:37'	System	19 Feb 2021 09:58:48

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751092

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751093

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-26T00:01:23-05:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '4fc2274a-e47e-42cd-949d-47c3858171a7'	System	26 Feb 2021 05:02:22
User entered 'No (N)'	System	26 Feb 2021 05:02:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-26T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '4fc2274a-e47e-42cd-949d-47c3858171a7'	System	26 Feb 2021 05:02:22
User entered 'No (N)'	System	26 Feb 2021 05:02:22

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-02-26T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '4fc2274a-e47e-42cd-949d-47c3858171a7'	System	26 Feb 2021 05:02:22
User entered '26 Feb 2021 00:01:28'	System	26 Feb 2021 05:02:22

FDA-CBER-2022-1614-1751097

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751098

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751099

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751105

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751107

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751108

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751109

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751110

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751111

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751112

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751113

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751114

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751115

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751116

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751117

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751118

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751119

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751120

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751121

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751125

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751126

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751127

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-12T18:56:58-05:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'edb4bab7-cf29-4bea-9dbc-d5f0f0f69bb9'	System	12 Mar 2021 23:57:07
User entered 'No (N)'	System	12 Mar 2021 23:57:07

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-12T18:57:01-05:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'edb4bab7-cf29-4bea-9dbc-d5f0f0f69bb9'	System	12 Mar 2021 23:57:07
User entered 'No (N)'	System	12 Mar 2021 23:57:07

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-12T18:57:04-05:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'edb4bab7-cf29-4bea-9dbc-d5f0f0f69bb9'	System	12 Mar 2021 23:57:07
User entered '12 Mar 2021 18:57:04'	System	12 Mar 2021 23:57:07

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751132

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751133

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751139

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751140

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751141

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751142

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751143

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751144

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751145

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751146

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751147

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751148

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751149

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751150

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751151

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751152

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751154

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751155

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751160

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751161

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:07:22

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:18-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered 'Yes (Y)'	System	26 Mar 2021 08:17:01

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

Have you been exposed to someone with 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)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:22-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered 'No (N)'	System	26 Mar 2021 08:17:01

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:27-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered 'Yes (Y)'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

FDA-CBER-2022-1614-1751169

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '1'	System	26 Mar 2021 08:17:01

FDA-CBER-2022-1614-1751171

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '1'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '1'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '1'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '1'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '1'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '1'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

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US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:38-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '0'	System	26 Mar 2021 08:17:01

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:41-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Mar 2021 08:17:01

US3402232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:47-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered 'No (N)'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4a3bb3f0c4253940)', Time: '2021-03-26T04:16:50-04:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: '6ace4603-9b22-49c5-b804-c8217e8974ed'	System	26 Mar 2021 08:17:01
User entered '26 Mar 2021 04:16:50'	System	26 Mar 2021 08:17:01

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751186

US3402232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:24:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:07:22
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:07:22

FDA-CBER-2022-1614-1751187

US3402232

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:24:33

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 (4a3bb3f0c4253940)', Time: '2021-03-12T18:56:50-05:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e16ca6a5-7afd-446e-ae28-e5ed414b8fe7'	System	12 Mar 2021 23:56:56
User entered 'No (N)'	System	12 Mar 2021 23:56:56

US3402232
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 09 Jun 2021 17:24:33
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 (4a3bb3f0c4253940)', Time: '2021-03-12T18:56:53-05:00', User OID: 'PatientReportedOutcome (US3402232)', ODM File OID: 'e16ca6a5-7afd-446e-ae28-e5ed414b8fe7'	System	12 Mar 2021 23:56:56
User entered '12 Mar 2021 18:56:53'	System	12 Mar 2021 23:56:56

US3402232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:21:46
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Oct 2020 15:47:11

US3402232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:21:46
User entered '28 Oct 2020'	Traci Hull (b) (4) (b) (4)	28 Oct 2020 15:47:11

US3402232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:21:46
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	28 Oct 2020 15:47:11

US3402232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:21:46
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Oct 2020 15:47:11

US3402232
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Mar 2021 22:21:46
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Oct 2020 15:46:59

US3402232
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:57
User entered '1'	System	28 Oct 2020 15:46:59

FDA-CBER-2022-1614-1751195

US3402232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 13:43:57

US3402232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '2 Dec 2020'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 13:43:57

FDA-CBER-2022-1614-1751197

US3402232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 13:43:57

US3402232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Dec 2020 13:43:57

FDA-CBER-2022-1614-1751199

US3402232
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	02 Dec 2020 13:44:05

FDA-CBER-2022-1614-1751200

US3402232
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User entered '1'	System	02 Dec 2020 13:44:05

FDA-CBER-2022-1614-1751201

US3402232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Dec 2020 14:54:02

FDA-CBER-2022-1614-1751202

US3402232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '30 Dec 2020'	Traci Hull (b) (4) (b) (4)	30 Dec 2020 14:54:02

US3402232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	30 Dec 2020 14:54:02

US3402232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Dec 2020 14:54:02

FDA-CBER-2022-1614-1751205

US3402232
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Dec 2020 14:53:52

FDA-CBER-2022-1614-1751206

US3402232
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User entered '1'	System	30 Dec 2020 14:53:52

FDA-CBER-2022-1614-1751207

US3402232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Feb 2021 16:16:53

US3402232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '27 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	03 Feb 2021 16:16:53

FDA-CBER-2022-1614-1751209

US3402232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	03 Feb 2021 16:16:53

US3402232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:24:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Feb 2021 16:16:53

FDA-CBER-2022-1614-1751211

US3402232
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Feb 2021 16:16:56

US3402232
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:05:10
User entered '1'	System	03 Feb 2021 16:16:56

FDA-CBER-2022-1614-1751213

US3402232
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 19:47:00

FDA-CBER-2022-1614-1751214

US3402232
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered '23 Feb 2021'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 19:47:00

US3402232
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
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 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 19:47:00

FDA-CBER-2022-1614-1751216

US3402232
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User entered 'VISIT4'	System	23 Feb 2021 19:47:00

FDA-CBER-2022-1614-1751217

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751219

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751220

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User entered empty.	System	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751221

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User entered empty.	System	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751226

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User entered empty.	System	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751228

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751229

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User entered empty.	System	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751230

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751231

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User entered empty.	System	31 Mar 2021 17:41:46

FDA-CBER-2022-1614-1751232

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13

FDA-CBER-2022-1614-1751233

US3402232
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13

FDA-CBER-2022-1614-1751234

US3402232
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 19:47:06

US3402232
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered empty.	Traci Hull (b) (4) (b) (4)	23 Feb 2021 19:47:06

FDA-CBER-2022-1614-1751236

US3402232
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	08 Mar 2021 15:30:30

FDA-CBER-2022-1614-1751237

US3402232
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered '23 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	08 Mar 2021 15:30:30

US3402232
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered '14:19'	Tammy Kohn (b) (4) (b) (4)	08 Mar 2021 15:30:30

US3402232
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User entered '23 Feb 2021 14:19'	System	08 Mar 2021 15:30:30

FDA-CBER-2022-1614-1751240

US3402232
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:53:10
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	23 Feb 2021 19:47:11

FDA-CBER-2022-1614-1751241

US3402232
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:24:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:46:13
User entered '1'	System	23 Feb 2021 19:47:11

FDA-CBER-2022-1614-1751242

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:24:33
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:18
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:01
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:35

FDA-CBER-2022-1614-1751243

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:24:33
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:18
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:01
User entered '14:00'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:35

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:24:33
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:18
User entered '26 Mar 2021 14:00'	System	29 Mar 2021 14:45:35

FDA-CBER-2022-1614-1751245

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:24:33
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:18
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:01
User closed query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 22:09:09
Query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' answered with 'UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 18:45:42
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 18:45:34
User opened query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 12:02:27
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:35

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:24:33
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:18
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:01
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:35

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 1 (Day 1)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

FDA-CBER-2022-1614-1751248

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '18 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:50:25

FDA-CBER-2022-1614-1751252

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

FDA-CBER-2022-1614-1751256

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (1)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:50:25

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 2 (Day 2)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

FDA-CBER-2022-1614-1751270

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '19 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:51:27

FDA-CBER-2022-1614-1751274

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

FDA-CBER-2022-1614-1751284

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

FDA-CBER-2022-1614-1751285

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

FDA-CBER-2022-1614-1751286

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (2)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:27

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

FDA-CBER-2022-1614-1751292

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '20 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:51:57

FDA-CBER-2022-1614-1751296

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

FDA-CBER-2022-1614-1751308

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (3)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:51:57

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 4 (Day 4)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '21 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

FDA-CBER-2022-1614-1751317

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:52:20

FDA-CBER-2022-1614-1751318

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

FDA-CBER-2022-1614-1751325

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

FDA-CBER-2022-1614-1751328

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

FDA-CBER-2022-1614-1751329

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (4)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:20

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '22 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

FDA-CBER-2022-1614-1751339

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:52:50

FDA-CBER-2022-1614-1751340

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

FDA-CBER-2022-1614-1751347

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

FDA-CBER-2022-1614-1751352

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (5)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:52:50

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 6 (Day 6)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '23 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

FDA-CBER-2022-1614-1751360

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:53:15

FDA-CBER-2022-1614-1751362

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

FDA-CBER-2022-1614-1751368

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (6)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:15

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

FDA-CBER-2022-1614-1751380

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '24 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:53:48

FDA-CBER-2022-1614-1751384

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

FDA-CBER-2022-1614-1751393

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

FDA-CBER-2022-1614-1751396

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (7)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:53:48

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 8 (Day 8)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

FDA-CBER-2022-1614-1751402

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '25 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:54:16

FDA-CBER-2022-1614-1751406

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

FDA-CBER-2022-1614-1751407

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

FDA-CBER-2022-1614-1751412

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

FDA-CBER-2022-1614-1751418

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (8)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:16

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

FDA-CBER-2022-1614-1751424

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '99'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

FDA-CBER-2022-1614-1751427

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	29 Mar 2021 14:54:59

FDA-CBER-2022-1614-1751428

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '36.9' C	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

FDA-CBER-2022-1614-1751429

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

FDA-CBER-2022-1614-1751434

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

FDA-CBER-2022-1614-1751438

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

FDA-CBER-2022-1614-1751440

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (9)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:54:59

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 10 (Day 10)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '27 Mar 2021'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '98'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

FDA-CBER-2022-1614-1751449

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	30 Mar 2021 12:49:11

FDA-CBER-2022-1614-1751450

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '97.8' F	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

FDA-CBER-2022-1614-1751460

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (10)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:11

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 11 (Day 11)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

FDA-CBER-2022-1614-1751468

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '28 Mar 2021'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '98'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

FDA-CBER-2022-1614-1751471

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	30 Mar 2021 12:49:36

FDA-CBER-2022-1614-1751472

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 12:51:14
User entered '97.6' F reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 12:49:36
User entered '97' (non-conformant).	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

FDA-CBER-2022-1614-1751473

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

FDA-CBER-2022-1614-1751486

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (11)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:14
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:49:36

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Day 12 (Day 12)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '29 Mar 2021'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '0'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '98'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User entered '%'	System	30 Mar 2021 12:51:47

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered '97.9' F	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Symptom Log (12)
Generated On: 09 Jun 2021 17:24:33
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:59:46
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:51:47

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
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 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 14:46:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 14:46:03
User entered 'Yes (Y)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:46:03
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 14:45:55
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
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 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
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)	20 Apr 2021 09:38:01
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 'SUBJECT TESTED POSITIVE FOR COVID BUT FAILED TO FOLLOW UP WITH STUDY. AFTER SEVERAL ATEMPTS TO HAVE THE SUBJECT COME INTO THE OFFICE. SUBJECT STATED HE NO LONGER WANTED TO PARTICIPATE. ' (Site from System).	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 14:59:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	15 Apr 2021 15:23:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	15 Apr 2021 15:23:58
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	06 Apr 2021 19:18:35
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 by data change (Site from System).	System	06 Apr 2021 19:18:35
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Apr 2021 19:18:35
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	03 Apr 2021 15:56:45

US3402232

Folder: Covid-19 Assessment 26 Mar 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:33

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:56:45
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

FDA-CBER-2022-1614-1751516

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

FDA-CBER-2022-1614-1751517

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

FDA-CBER-2022-1614-1751518

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33

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 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

FDA-CBER-2022-1614-1751519

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

FDA-CBER-2022-1614-1751520

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:29:50
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:45:55

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 17:24:33
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:40
User entered '1'	System	15 Apr 2021 15:23:58
User entered '0'	System	06 Apr 2021 19:18:35
User entered '1'	System	03 Apr 2021 15:56:45
User entered '0'	System	29 Mar 2021 14:45:55

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751525

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751526

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751528

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

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US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
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 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751533

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751534

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751535

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751536

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751537

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751538

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751542

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751546

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751548

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751550

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751551

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751554

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751556

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751557

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751560

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751561

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751564

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751565

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751569

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
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 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

US3402232
Folder: Covid-19 Assessment 26 Mar 2021
Form: Covid-19 Severity Assessment
Generated On: 09 Jun 2021 17:24:33
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:33:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:28:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:03

FDA-CBER-2022-1614-1751573

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 17:24:33
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751574

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 17:24:33
Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	03 May 2021 22:58:20
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	29 Apr 2021 15:45:12
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	29 Apr 2021 15:45:12
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 12:38:01
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:36
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 17:24:33
Date of Collection

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4) (b) (4)	03 May 2021 22:58:20
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 26MAR2021 is missing in PPD. Please confirm if the sample has been collected and shipped to PPD or not.' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 03:54:28
Query 'Per GCL LAB reconciliation: Saliva: Sample dated 26MAR2021 is missing in PPD. Please confirm if the sample has been collected and shipped to PPD or not.' answered with 'subject came in on the 26th initial visit however refused to comply with convalescent protocol. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	29 Apr 2021 15:46:00
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	29 Apr 2021 15:45:12
User entered empty; reason for change New Information	Tammy Kohn (b) (4) (b) (4)	29 Apr 2021 15:45:12
User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 26MAR2021 is missing in PPD. Please confirm if the sample has been collected and shipped to PPD or not.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:48:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '26 Mar 2021' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	20 Apr 2021 12:38:01
User entered empty; reason for change New Information	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:58:36
User entered '28 Mar 2021'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 17:24:33
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751577

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 17:24:33
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 17:24:33
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 17:24:33
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751580

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 17:24:33
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 17:24:33
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751582

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 17:24:33
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751583

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 17:24:33
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 17:24:33
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751585

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 17:24:33
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751586

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 17:24:33
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 17:24:33
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751588

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 17:24:33
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751589

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 17:24:33
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 17:24:33
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751591

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 17:24:33
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751592

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 17:24:33
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

US3402232
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 17:24:33
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Mar 2021 12:52:27

FDA-CBER-2022-1614-1751594

US3402232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:09
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:11

US3402232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:09
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:11

FDA-CBER-2022-1614-1751596

US3402232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:09
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:11

US3402232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered 'SICKD1'	System	29 Mar 2021 14:55:11

FDA-CBER-2022-1614-1751598

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered '14:13'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '26 Mar 2021 14:13'	System	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751602

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47
DataPoint set to visible.	System	29 Mar 2021 14:55:11

FDA-CBER-2022-1614-1751603

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47
DataPoint set to visible.	System	29 Mar 2021 14:55:11

FDA-CBER-2022-1614-1751604

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered '36.9' C	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751607

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered '66'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751608

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered 'bpm'	System	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751609

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered '14'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751610

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered 'breaths/min'	System	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751611

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered '126'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751612

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered 'mmHg'	System	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751613

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:27:04
User entered '86'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:47

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered 'mmHg'	System	29 Mar 2021 14:55:47

FDA-CBER-2022-1614-1751615

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751616

US3402232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:24:33
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751617

US3402232
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:56
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:59

US3402232
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:24:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:56
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:55:59

US3402232
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 17:24:33
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:23
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:56:11

US3402232
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 17:24:33
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:23
User entered '26 Mar 2021'	Traci Hull (b) (4) (b) (4)	29 Mar 2021 14:56:11

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:08

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '12 Jan 2021'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:08

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
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 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:08

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US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:24:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 19:04:08

FDA-CBER-2022-1614-1751625

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '06 Jan 2021'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:54

FDA-CBER-2022-1614-1751626

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
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 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '0'	Tammy Kohn (b) (4) (b) (4)	08 Mar 2021 15:38:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:28:39

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US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:54

FDA-CBER-2022-1614-1751628

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (b) (4)	08 Mar 2021 15:38:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:28:39

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '12 Jan 2021'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:54

FDA-CBER-2022-1614-1751630

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'mRNA-1273 (mRNA-1273)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:54

FDA-CBER-2022-1614-1751631

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 06:18:39
User entered 'mRNA-1273 (mRNA-1273)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:54

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 06:18:39
User entered 'mRNA-1273 (mRNA-1273)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:54

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:04:54

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User entered empty.	System	12 Jan 2021 19:04:54

FDA-CBER-2022-1614-1751635

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:24:33
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User entered empty.	System	12 Jan 2021 19:04:54

FDA-CBER-2022-1614-1751636

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:05:07

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '12 Jan 2021'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:05:07

FDA-CBER-2022-1614-1751638

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '13:45'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:05:07

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:24:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User entered '12 Jan 2021 13:45'	System	12 Jan 2021 19:05:07

FDA-CBER-2022-1614-1751640

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:24:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:05:22

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:24:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '12 Jan 2021'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:05:22

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:24:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '13:47'	Traci Hull (b) (4) (b) (4)	12 Jan 2021 19:05:22

FDA-CBER-2022-1614-1751643

US3402232
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 17:24:33
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:43:57
User entered '12 Jan 2021 13:47'	System	12 Jan 2021 19:05:22

US3402232
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 17:24:33
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:10:30
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
Signature has been broken.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:59:03
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 15:59:03
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:40:55
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:45:32

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:26
User entered 'USA-US059-2021-mRNA-1273-P301000013'	System	05 Apr 2021 13:21:22
User entered 'New'	(b) (4), (b) (6)	05 Apr 2021 13:21:22

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User closed query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:06:04
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:06:02
Query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' answered with 'UNABLE TO COMPLETE ANY FURTHER INFORMATION AS THE SUBJECT WITHDREW CONSENT ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:57:28
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'UNABLE TO COMPLETE ANY FURTHER INFORMATION AS THE SUBJECT WITHDREW CONSENT ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:57:25

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Adverse event

Audit	User	Time (GMT)
User opened query 'PV Query: Please note that events of COVID-19 are collected as a standard per protocol; therefore, this event should not be reported as an SAE based on the seriousness criterion of "Other medically important event". Please reassess whether this event meets the standard definitions for an SAE and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 21:10:20
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 21:10:00
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:40:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:40:48
Data point term sent to Coder	System	03 Apr 2021 16:01:40
User entered 'Sars Covid 2'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '18 Mar 2021' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:05:29
User entered '16 Mar 2021'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered empty.	System	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Apr 2021 00:03:55
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:59:05
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:59:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Apr 2021 00:03:55
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	13 Apr 2021 09:54:04
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'ENDED AS OF DATE THE SUBJECT WITHDREW CONSENT 26MAR2021' (Site from System).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:59:52
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Apr 2021 16:59:05
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:59:05
User entered '26 Mar 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:59:05
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered empty.	System	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751660

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751661

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751663

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751664

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751665

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751666

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751667

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751669

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751670

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751671

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 16:01:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Apr 2021 16:01:49
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:49
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 16:01:19
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751674

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751675

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

FDA-CBER-2022-1614-1751676

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Apr 2021 00:03:55
User closed query 'Per CDM re-query: Outcome is recorded as UNKNOWN; However AE end date provided. Please update the outcome as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 07:26:45
Query 'Per CDM re-query: Outcome is recorded as UNKNOWN; However AE end date provided. Please update the outcome as appropriate else clarify.' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 14:27:47
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 14:27:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 14:27:43
User opened query 'Per CDM re-query: Outcome is recorded as UNKNOWN; However AE end date provided. Please update the outcome as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 09:54:01
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	03 Apr 2021 16:05:29
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	03 Apr 2021 16:01:19
User entered 'Unknown (UNKNOWN)'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty; reason for change Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:05:29
User entered 'Subject has withdrawn consent from trial.'	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:42
User closed query 'PV Query: Please provide the date that the subject withdrew consent from the trial.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:06:14
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:06:10
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'UNABLE TO COMPLETE ANY FURTHER INFORMATION AS THE SUBJECT WITHDREW CONSENT ' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:57:33
Query 'PV Query: Please provide the date that the subject withdrew consent from the trial.' answered with '26 MAR 2021' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:56:42
User opened query 'PV Query: Please provide the date that the subject withdrew consent from the trial.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 21:11:20
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 21:09:41
Query 'Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 21:09:29
User opened query 'Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 21:09:24
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'SUBJECT DEVELOPED COVID SYMPTOMS 18 MAR 2021. Subject advised site of symptoms 24Mar2021, and was seen for illness visit 26Mar2021. After being followed for 4 days subject then withdrew consent from trial.' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:05:29

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Narrative

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Apr 2021 16:02:44
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Apr 2021 16:02:44
User entered 'Subject developed covid symptoms 16 mar 2021.' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:02:44
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Apr 2021 16:01:19
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '1'	System	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '1'	System	03 Apr 2021 16:01:19

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US3402232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:24:33
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47

FDA-CBER-2022-1614-1751683

US3402232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:24:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:11
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User closed query 'Per DM CLR: Per Diary Dose 2 Day 12, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 13:25:29
Query 'Per DM CLR: Per Diary Dose 2 Day 12, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'INJECTION SITE PAIN ADDED TO CONMEDS.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:49
User opened query 'Per DM CLR: Per Diary Dose 2 Day 12, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:33:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:45:43

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:20:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:20:00
Data point term sent to Coder	System	05 Aug 2020 17:19:39
Data point term sent to Coder	System	05 Aug 2020 16:46:52
User entered 'multivitamin'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

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US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

FDA-CBER-2022-1614-1751686

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 17:19:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 17:19:03
User entered 'dietary supplement' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	05 Aug 2020 17:19:03
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 16:46:49
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '1'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'tablet (TABLET)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

FDA-CBER-2022-1614-1751693

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
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)	14 Aug 2020 16:36:44
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)	05 Aug 2020 17:20:13
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	05 Aug 2020 16:46:49
User entered 'un UNK 2016'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

FDA-CBER-2022-1614-1751695

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 16:46:49

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '1'	System	05 Aug 2020 16:46:49

FDA-CBER-2022-1614-1751700

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '1'	System	05 Aug 2020 16:46:49

FDA-CBER-2022-1614-1751701

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:24:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '804 (804)'	System	05 Aug 2020 16:46:49

FDA-CBER-2022-1614-1751702

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 20:58:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 20:58:56
Data point term sent to Coder	System	18 Feb 2021 20:43:06
User entered 'IBUPROFEN'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751703

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751704

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:12:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'NO AE OR SAE AS THIS IS WITHIN THE 7 DAYS OF INJECTION' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	01 Mar 2021 14:41:30

FDA-CBER-2022-1614-1751705

US3402232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:33

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:33:11
User entered 'PAIN AT INJECTION SITE'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '200'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'mg (mg)'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751708

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'as needed (PRN)'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751710

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751711

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751713

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '03 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '0'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered '09 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751717

US3402232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:33

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:19:46
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User closed query ' Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:12:57
Query ' Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'UPDATED TO YES' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	01 Mar 2021 14:41:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	01 Mar 2021 14:41:35
User opened query ' Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:33:30
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	18 Feb 2021 20:42:17

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
User entered empty.	System	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751719

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
User entered empty.	System	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751720

US3402232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:24:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:19:37
User entered empty.	System	18 Feb 2021 20:42:17

FDA-CBER-2022-1614-1751721

US3402232
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 17:24:33
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:47:32
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:32:40
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Aug 2020 17:20:30

FDA-CBER-2022-1614-1751722

US3402232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:24:33
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered '26 Mar 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 16:58:11
User entered '1 Apr 2021'	Jennifer Molstead (b) (4) (b) (4)	01 Apr 2021 21:02:05

US3402232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:24:33
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Jennifer Molstead (b) (4) (b) (4)	01 Apr 2021 21:02:05

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US3402232

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:24:33

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered 'Subject refused to comply with convalescent period requirements .'	Jennifer Molstead (b) (4) (b) (4)	01 Apr 2021 21:02:05

US3402232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:24:33
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Apr 2021 21:02:05

FDA-CBER-2022-1614-1751726

US3402232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:24:33
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Apr 2021 21:02:05

FDA-CBER-2022-1614-1751727

US3402232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:24:33
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Apr 2021 21:02:05

FDA-CBER-2022-1614-1751728

US3402232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:24:33
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:19
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Apr 2021 21:02:05

FDA-CBER-2022-1614-1751729

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'USA-US059-2021-MRNA-1273-P301000013'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Yes (Y)'	System	05 Apr 2021 13:21:22

FDA-CBER-2022-1614-1751731

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Yes (Y)'	System	05 Apr 2021 13:21:22

FDA-CBER-2022-1614-1751737

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Frank'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Eder'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered '1290 Upper Front Street'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Binghamton'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'NY'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered '13901'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:06:29
User entered 'US'	System	05 Apr 2021 13:21:51

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '2'	System	13 Apr 2021 16:06:39
User entered '1'	System	05 Apr 2021 13:21:51

FDA-CBER-2022-1614-1751745

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'USA-US059-2021-MRNA-1273-P301000013'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Yes (Y)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Yes (Y)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Frank'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Eder'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered '1290 Upper Front Street'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Binghamton'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'NY'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered '13901'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:06:29
User entered 'US'	System	05 Apr 2021 13:21:51

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '2'	System	13 Apr 2021 16:06:39
User entered '1'	System	05 Apr 2021 13:21:51

FDA-CBER-2022-1614-1751761

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 17:24:33
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
User entered '05/Apr/2021 13:21'	System	05 Apr 2021 13:21:51

US3402232

Folder: SAE USA-US059-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:06:29
User entered '1'	(b) (4), (b) (6)	05 Apr 2021 13:21:51

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'USA-US059-2021-MRNA-1273-P301000013'	System	05 Apr 2021 13:21:22

FDA-CBER-2022-1614-1751764

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Yes (Y)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'No (N)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Yes (Y)'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Frank'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Eder'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered '1290 Upper Front Street'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'Binghamton'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered 'NY'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:21:41
User entered '13901'	System	05 Apr 2021 13:21:22

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:06:29
User entered 'US'	System	05 Apr 2021 13:21:51

FDA-CBER-2022-1614-1751778

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 09 Jun 2021 17:24:33
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User entered '2'	System	13 Apr 2021 16:06:39
User entered '1'	System	05 Apr 2021 13:21:51

FDA-CBER-2022-1614-1751779

US3402232
Folder: SAE USA-US059-2021-MRNA-1273-P301000013
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 17:24:33
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
User entered '13/Apr/2021 12:06'	System	13 Apr 2021 16:06:39

US3402232

Folder: SAE USA-US059-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:33

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:48:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:52:34
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:26
User entered '1'	(b) (4), (b) (6)	13 Apr 2021 16:06:39