US3492299 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:46:51

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US3492299
Form: Participant Creation
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Participant ID	US3492299

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-2473066

US3492299
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-2473067

US3492299
Folder: Screening
Form: Demographics
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
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-2022-1614-2473068

US3492299
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Date of Informed Consent *(dd MMM yyyy)*	13 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ■ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

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US3492299
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473070

US3492299
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-2473071

US3492299
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Condition	LOW TESTOSTERONE - HYPOGONADISM
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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US3492299
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	
Stop Year (derived)	

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US3492299
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	13 OCT 2020
Time of assessment *(00:00-23:59)*	12:15 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:15
Height *(xxx.x)*	169 cm
Weight *(xxx.x)*	75 kg
BMI *(xxx.x)*	26.25958 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)	

US3492299
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	13 OCT 2020

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

FDA-CBER-2022-1614-2473075

US3492299
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 04:37:24**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ■
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ■ No ☐
Specify	REAL ESTATE, PROPERTY MANAGER

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

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

US3492299
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-2473078

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

What was the date of randomization? *(dd MMM yyyy)*	13 OCT 2020
What was the participant's randomization number?	116763
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 ●
Human Immunodeficiency Virus (HIV) infection	Yes ○ No ●

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US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 04:37:24**
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Height	ND - Not Done
Weight	ND - Not Done

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US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

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)*	13 OCT 2020
Time of assessment *(00:00-23:59)*	12:05 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:05
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	NOT SPECIFIED
Pulse *(xxx)*	83 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG

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US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

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)*	13 OCT 2020
Time of assessment *(00:00-23:59)*	14:00 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:00
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	NOT SPECIFIED
Pulse *(xxx)*	79 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	73 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2473082

US3492299
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	13 OCT 2020

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

FDA-CBER-2022-1614-2473083

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

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)*	13 OCT 2020
What was the treatment time? *(00:00-23:59)*	13:28 (24 HR)
Treatment Date and Time (derived)	13 OCT 2020 13:28
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-2022-1614-2473084

US3492299
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	13 OCT 2020
Collection time *(00:00-23:59)*	13:05 (24 HR)
Collection date and time (derived)	13 OCT 2020 13:05

FDA-CBER-2022-1614-2473085

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Collection date *(dd MMM yyyy)*			13 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:15	13 OCT 2020 13:15
Nasopharyngeal Swab 2	No		

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US3492299
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473087

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:51

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**	98.4 °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	13 OCT 2020 14:16
PC Open Date & Time	13 OCT 2020 13:48
PC Close Date & Time	13 OCT 2020 16:18

FDA-CBER-2022-1614-2473088

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:51

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**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 OCT 2020 10:07
PC Open Date & Time	13 OCT 2020 17:13
PC Close Date & Time	14 OCT 2020 11:59

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US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:51

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**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 OCT 2020 14:17
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:51

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	15 OCT 2020 15:17
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

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US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 OCT 2020 15:04
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:51

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**	98.5 °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	17 OCT 2020 12:40
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:51

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**	96.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 OCT 2020 17:33
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

FDA-CBER-2022-1614-2473094

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:51

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**	97.6 °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	19 OCT 2020 12:01
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51

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	13 OCT 2020 14:17
PC Open Date & Time	13 OCT 2020 13:48
PC Close Date & Time	13 OCT 2020 16:18

FDA-CBER-2022-1614-2473096

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51

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	14 OCT 2020 10:08
PC Open Date & Time	13 OCT 2020 17:13
PC Close Date & Time	14 OCT 2020 11:59

FDA-CBER-2022-1614-2473097

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51

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	14 OCT 2020 14:17
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

FDA-CBER-2022-1614-2473098

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51

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	15 OCT 2020 15:17
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51

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	16 OCT 2020 15:04
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51

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	17 OCT 2020 12:40
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51

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	18 OCT 2020 17:33
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

FDA-CBER-2022-1614-2473102

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51

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	19 OCT 2020 12:01
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

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 ☐

FDA-CBER-2022-1614-2473104

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	13 OCT 2020 14:17
PC Open Date & Time	13 OCT 2020 13:48
PC Close Date & Time	13 OCT 2020 16:18

FDA-CBER-2022-1614-2473105

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
HEADACHE	● None
	☐ No interference with activity
	☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
	☐ Any use of prescription pain reliever or prevents daily activity
FATIGUE	● None
	☐ No interference with activity
	☐ Some interference with activity
	☐ Significant; prevents daily activity
MUSCLE ACHES ALL OVER BODY	● None
	☐ No interference with activity
	☐ Some interference with activity
	☐ Significant; prevents daily activity
JOINT ACHES IN SEVERAL JOINTS	● None
	☐ No interference with activity
	☐ Some interference with activity
	☐ Significant; prevents daily activity
NAUSEA/VOMITING	● None
	☐ No interference with activity or 1-2 episodes/24 hours
	☐ Some interference with activity or >2 episodes/24 hours
	☐ Prevents daily activity, requires outpatient IV hydration
CHILLS	● None
	☐ No interference with activity
	☐ Some interference with activity not requiring medical attention
	☐ Prevents daily activity and requires medical attention

FDA-CBER-2022-1614-2473106

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	14 OCT 2020 10:08
PC Open Date & Time	13 OCT 2020 17:13
PC Close Date & Time	14 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51

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 ■

FDA-CBER-2022-1614-2473108

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51

	Yes ☐
PC Time stamp	14 OCT 2020 14:18
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51

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-2022-1614-2473110

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51

	Yes ☐
PC Time stamp	15 OCT 2020 15:17
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 4
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-2473112

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51

	Yes ☐
PC Time stamp	16 OCT 2020 15:04
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

FDA-CBER-2022-1614-2473113

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473114

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51

	Yes ☐
PC Time stamp	17 OCT 2020 12:40
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

FDA-CBER-2022-1614-2473115

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51

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-2022-1614-2473116

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51

	Yes ☐
PC Time stamp	18 OCT 2020 17:33
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

FDA-CBER-2022-1614-2473117

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 7
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-2473118

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51

	Yes ☐
PC Time stamp	19 OCT 2020 12:01
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

FDA-CBER-2022-1614-2473119

US3492299
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473120

US3492299
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

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

US3492299
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 OCT 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	THREE CALL ATTEMPTS MADE. ALTERNATE CONTACT DID NOT ANSWER CALL, VOICEMAIL LEFT.

FDA-CBER-2022-1614-2473122

US3492299
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473123

US3492299
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 NOV 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-2022-1614-2473124

US3492299
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473125

US3492299
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473126

US3492299
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51

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

US3492299
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51

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

US3492299
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51

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-2022-1614-2473129

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

Was study treatment given?	Yes ☐ No ■
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ■ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	
What was the treatment date? *(dd MMM yyyy)*	
What was the treatment time? *(00:00-23:59)*	
Treatment Date and Time (derived)	
Which arm was used to give treatment?	Left Arm ☐ Right Arm ☐
What was the frequency of the study treatment dosing?	
What was the route of administration for the study treatment?	

FDA-CBER-2022-1614-2473130

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

Collection date *(dd MMM yyyy)*

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3492299
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 04:37:24**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473133

US3492299
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 NOV 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-2022-1614-2473134

US3492299
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473135

US3492299
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

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	SUBJECT MIA

If Contact Not Made, please provide Comments

FDA-CBER-2022-1614-2473136

US3492299
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473137

US3492299
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

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*	SUBJECT MIA DESPITE MULTIPLE CONTACT ATTEMPTS THOUGHT MIA PERIOD

US3492299
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473139

US3492299
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 16:36:14**
Generated On: 11 Aug 2021 22:46:51

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	VISIT3

FDA-CBER-2022-1614-2473140

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 16:36:14**
Generated On: 11 Aug 2021 22:46:51

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-2022-1614-2473141

US3492299
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 16:36:14**
Generated On: 11 Aug 2021 22:46:51

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-2022-1614-2473142

US3492299
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

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

US3492299
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473144

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■

FDA-CBER-2022-1614-2473145

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately
Date and time of submission	10 DEC 2020 07:53:33
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

FDA-CBER-2022-1614-2473146

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 06:38:01
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

FDA-CBER-2022-1614-2473147

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-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	24 DEC 2020 09:47:30
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

FDA-CBER-2022-1614-2473150

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-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	10 JAN 2021 18:26:35
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

FDA-CBER-2022-1614-2473151

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 16:57:27
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3492299
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 11 Aug 2021 22:46:51

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

US3492299
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 JAN 2021
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	SUBJECT MIA

FDA-CBER-2022-1614-2473154

US3492299
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 16:36:13**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473155

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID-19 Contact
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Date of Contact	12 NOV 2020
Time of Contact	11:00
Date and Time of Contact (derived)	12 NOV 2020 11:00
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 ☐

FDA-CBER-2022-1614-2473156

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-2022-1614-2473157

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	10 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473159

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 ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

Symptom Day

- [ ] Day 1
- [x] 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
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- [ ] Day 26
- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-2473161

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	11 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [x] 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
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- [ ] Day 27
- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	12 NOV 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	96.8 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-2473168

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [x] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
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- [ ] Day 28
- [ ] Day 29
- [ ] Day 30
- [ ] Day 31
- [ ] Day 32

FDA-CBER-2022-1614-2473169

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	13 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473171

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [x] 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-2022-1614-2473173

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	14 NOV 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.5 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473175

Nasal Congestion	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-2473176

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-2022-1614-2473177

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	15 NOV 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	97.5 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473179

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473181

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	16 NOV 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	97.8 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473183

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473185

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	17 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473187

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473189

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	18 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-2473192

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-2022-1614-2473193

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	19 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

FDA-CBER-2022-1614-2473194

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473197

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	_____
Assessment Not Done	_____
O2 Saturation	_____
O2 Saturation Units	_____
Temperature	_____
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Date of Visit	12 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ■
Date of Test	12 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Generate Next COVID-19 Assessment	Yes ■ No ☐

FDA-CBER-2022-1614-2473202

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID-19 Contact
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Date of Contact	20 NOV 2020
Time of Contact	09:30
Date and Time of Contact (derived)	20 NOV 2020 09:30
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ■ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ■ No ☐

FDA-CBER-2022-1614-2473203

Symptom Day

- [ ] Day 1
- [ ] Day 2
- [ ] Day 3
- [ ] Day 4
- [ ] Day 5
- [ ] Day 6
- [ ] Day 7
- [ ] Day 8
- [ ] Day 9
- [ ] Day 10
- [x] 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-2022-1614-2473204

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	20 NOV 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	99.7 F
Chills	None ☐ Mild ☐ Moderate ■ Severe ☐ Not Done ☐
Cough	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473206

Nasal Congestion	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-2473207

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-2022-1614-2473208

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	21 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473212

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	22 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473214

Nasal Congestion	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Runny Nose (Rhinorrhea)	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Nausea	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Vomiting	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Diarrhea	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Sore Throat	None ☐ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐

FDA-CBER-2022-1614-2473215

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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-2022-1614-2473216

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	23 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473220

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	24 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473224

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	25 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473226

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 ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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-2022-1614-2473228

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	26 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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-2022-1614-2473232

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	27 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473236

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	28 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473240

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	29 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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
- [x] 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-2022-1614-2473244

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	30 NOV 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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-2022-1614-2473248

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	1 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473252

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	2 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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-2022-1614-2473256

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	3 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473260

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	4 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Data signed: (b) (4) **15 Feb 2021 04:37:22**
Generated On: 11 Aug 2021 22:46:51

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Symptom Day

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

FDA-CBER-2022-1614-2473264

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	5 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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
- [x] 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	6 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

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	7 DEC 2020
Assessment Not Done	True
O2 Saturation	
O2 Saturation Units	
Temperature	
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

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

Nasal Congestion	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Date of Visit	20 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Date of Test	20 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

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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	

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Hepatic Dysfunction?	Yes ☐ No ☐
Start Date	
Neurologic Dysfunction?	Yes ☐ No ☐
Start Date	

Evidence of Pneumonia:

Clinical Evidence	Yes ☐ No ■
Date of Assessment	
Radiographical Evidence	Yes ☐ No ☐
Date of Assessment	

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

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

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	

FDA-CBER-2022-1614-2473281

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-2473282

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Were vital signs assessed?	Yes ● / No ○
Date of assessment *(dd MMM yyyy)*	12 NOV 2020
Time of assessment *(00:00-23:59)*	11:00 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 11:00
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	96.8 F
Route of measurement	Oral ● / Axillary ○ / Other ○
If Other, specify	
Pulse *(xxx)*	85 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2473283

US3492299
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	12 NOV 2020

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

FDA-CBER-2022-1614-2473284

US3492299
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	12 NOV 2020

FDA-CBER-2022-1614-2473285

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	20 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ■ Clinic ☐
Folder OID	SICKD1

FDA-CBER-2022-1614-2473286

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 NOV 2020
Time of assessment *(00:00-23:59)*	15:57 (24 HR)
Vital Signs Date and Time (derived)	20 NOV 2020 15:57
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	99.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	95 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492299
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	20 NOV 2020

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

FDA-CBER-2022-1614-2473288

US3492299
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	20 NOV 2020

FDA-CBER-2022-1614-2473289

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Was this visit performed?	Yes ☐ No ■
Visit date (dd MMM yyyy)	
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☐
Folder OID	SICKD28

FDA-CBER-2022-1614-2473290

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

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)	

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

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-2022-1614-2473292

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

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

FDA-CBER-2022-1614-2473293

US3492299
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **26 Mar 2021 01:57:41**
Generated On: 11 Aug 2021 22:46:51

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	UNBLND_DECIDE

FDA-CBER-2022-1614-2473294

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

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

US3492299
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

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

If Yes, enter details on the Adverse Events form.

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US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

AEID	USA-US101-2020-MRNA-1273-P301000008
Adverse event	COVID-19
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ■ No ☐
Start date *(dd MMM yyyy)*	10 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ■ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ■ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

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

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

FDA-CBER-2022-1614-2473300

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Name of Medication	TESTOSTERONE CYPIONATE
Prophylaxis	Yes ☐ No ■
Indication	HYPOGONADISM
Dose per administration	100
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 ☐

FDA-CBER-2022-1614-2473301

	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 2012
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 ☐

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Name of Medication	HCG
Prophylaxis	Yes ☐ No ■
Indication	HYPOGONADISM
Dose per administration	150
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	TWICE A WEEK
Route of administration	Oral ☐ Topical ☐ Subcutaneous ■ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2473303

	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 2010
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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Name of Medication	LORATIDINE
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
Dose per administration	10
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2473305

	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 2010
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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ■
Indication	FEVERS - COVID 19
Dose per administration	500
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ■ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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	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)*	20 NOV 2020
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)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3492299
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **15 Feb 2021 04:37:21**
Generated On: 11 Aug 2021 22:46:51

Were any concomitant procedures performed?	Yes ☐
	No ■

If yes, please complete Concomitant Procedures form.

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US3492299
Folder: End of Study (1)
Form: Dosing Discontinuation
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Date of dosing discontinuation (dd MMM yyyy)	25 NOV 2020
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ■ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

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US3492299
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

Date of study discontinuation/completion *(dd MMM yyyy)*	20 JAN 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	
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 ☐

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US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

SAEID	USA-US101-2020-MRNA-1273-P301000008
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form (1)
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

SAEID	USA-US101-2020-MRNA-1273-P301000008
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/DEC/2020 18:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-2473313

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form (2)
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

SAEID	USA-US101-2020-MRNA-1273-P301000008
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/DEC/2020 11:10
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

FDA-CBER-2022-1614-2473314

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form (3)
Data signed: (b) (4) **15 Feb 2021 04:37:23**
Generated On: 11 Aug 2021 22:46:51

SAEID	USA-US101-2020-MRNA-1273-P301000008
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	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/JAN/2021 00:12
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

US3492299
Form: Participant Creation
Generated On: 11 Aug 2021 22:46:51
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'US3492299'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:43:51

US3492299
Form: Participant Creation
Generated On: 11 Aug 2021 22:46:51

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2473318

US3492299
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:26:51

US3492299
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:43:52

FDA-CBER-2022-1614-2473320

US3492299
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 00:26:51

US3492299
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'SCRN'	(b) (4), (b) (6) System	15 Oct 2020 00:26:51

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:43:53

FDA-CBER-2022-1614-2473323

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '55'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'YEARS'	(b) (4), (b) (6) System	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '55'	(b) (4), (b) (6) System	13 Oct 2020 19:14:28

FDA-CBER-2022-1614-2473326

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Male (M)'	(b) (4), (b) (6)	15 Oct 2020 00:31:02

FDA-CBER-2022-1614-2473327

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '1'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:31:02

FDA-CBER-2022-1614-2473330

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:31:02

FDA-CBER-2022-1614-2473331

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:51
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:02

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 19:14:28

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'Oct 2020'	(b) (4), (b) (6) System	13 Oct 2020 19:14:28

FDA-CBER-2022-1614-2473339

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '2020'	(b) (4), (b) (6) System	13 Oct 2020 19:14:28

FDA-CBER-2022-1614-2473340

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	13 Oct 2020 19:14:28

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US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:14:28

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:14:28

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:14:28

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:14:28

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 17:43:52

FDA-CBER-2022-1614-2473346

US3492299
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:51
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '1'	(b) (4), (b) (6) System	13 Oct 2020 19:14:34

FDA-CBER-2022-1614-2473347

US3492299
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 11 Aug 2021 22:46:51
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:14:34

FDA-CBER-2022-1614-2473348

US3492299
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:46:51
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:32:59

FDA-CBER-2022-1614-2473349

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:38:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:38:50
Data point term sent to Coder	System	15 Oct 2020 00:36:22
User entered 'low testosterone - hypogonadism'	(b) (4), (b) (6)	15 Oct 2020 00:35:42

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'un UNK 2005'	(b) (4), (b) (6)	15 Oct 2020 00:35:42

FDA-CBER-2022-1614-2473351

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:35:42

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:35:42

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:35:42

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:35:42

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'Jan 2005'	(b) (4), (b) (6) System	15 Oct 2020 00:35:42

FDA-CBER-2022-1614-2473356

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '2005'	(b) (4), (b) (6) System	15 Oct 2020 00:35:42

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered empty.	(b) (4), (b) (6) System	15 Oct 2020 00:35:42

US3492299
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered empty.	(b) (4), (b) (6) System	15 Oct 2020 00:35:42

FDA-CBER-2022-1614-2473359

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:37:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:37:24
Data point term sent to Coder	System	15 Oct 2020 00:36:22
User entered 'seasonal allergies'	(b) (4), (b) (6)	15 Oct 2020 00:35:59

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	15 Oct 2020 00:36:04
User entered 'UN UNK 1966' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:36:04
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	15 Oct 2020 00:35:59
User entered 'un UNK 1965'	(b) (4), (b) (6)	15 Oct 2020 00:35:59

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:35:59

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:35:59

FDA-CBER-2022-1614-2473363

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:35:59

FDA-CBER-2022-1614-2473364

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:35:59

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'Jan 1966'	(b) (4), (b) (6) System	15 Oct 2020 00:36:04
User entered 'Jan 1965'	System	15 Oct 2020 00:35:59

FDA-CBER-2022-1614-2473366

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
	(b) (4), (b) (6)	
User entered '1966'	System	15 Oct 2020 00:36:04
User entered '1965'	System	15 Oct 2020 00:35:59

FDA-CBER-2022-1614-2473367

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered empty.	(b) (4), (b) (6) System	15 Oct 2020 00:35:59

US3492299
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered empty.	(b) (4), (b) (6) System	15 Oct 2020 00:35:59

FDA-CBER-2022-1614-2473369

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '12:15'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '13 Oct 2020 12:15'	(b) (4), (b) (6) System	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '169' cm	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:28:03
DataPoint set to visible.	System	13 Oct 2020 19:14:34

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '75' kg	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:28:03
DataPoint set to visible.	System	13 Oct 2020 19:14:34

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
	(b) (4), (b) (6)	
User entered '26.25958'	System	15 Oct 2020 00:28:03
DataPoint set to visible.	System	13 Oct 2020 19:14:34

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	15 Oct 2020 00:28:03
DataPoint set to visible.	System	13 Oct 2020 19:14:34

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'bpm'	(b) (4), (b) (6) System	15 Oct 2020 00:28:03

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US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'mmHg'	(b) (4), (b) (6) System	15 Oct 2020 00:28:03

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US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 00:28:03

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'mmHg'	(b) (4), (b) (6) System	15 Oct 2020 00:28:03

FDA-CBER-2022-1614-2473388

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59

FDA-CBER-2022-1614-2473389

US3492299
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59

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US3492299
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:27:28

US3492299
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:27:28

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US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'real estate, property manager'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:51
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:31:46

US3492299
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 17:44:33

US3492299
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 17:44:33

US3492299
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
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 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 17:44:33

US3492299
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'VISIT1'	(b) (4), (b) (6) System	13 Oct 2020 17:44:33

FDA-CBER-2022-1614-2473417

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 18:04:10

FDA-CBER-2022-1614-2473418

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '116763'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 18:04:10

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Oct 2020 18:04:10

FDA-CBER-2022-1614-2473420

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
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)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 17:45:28

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
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)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 17:45:28

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 17:45:28

FDA-CBER-2022-1614-2473423

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 17:45:28

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 17:45:28

US3492299
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:51
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 19:14:52
DataPoint set to visible.	System	13 Oct 2020 19:14:28

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:51
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473427

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:51
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:51
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:51
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473431

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473432

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473433

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '12:05'	(b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473434

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '13 Oct 2020 12:05'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '36.3' C	(b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473436

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Other (Other)'	(b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'not specified'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '83'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473439

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'bpm'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473440

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '16'	(b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473441

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473442

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '130'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473443

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'mmHg'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473444

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '85'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473445

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'mmHg'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473446

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:51
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:51
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered missing code ND - Not Done.	(b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473451

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '14:00'	(b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473452

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '13 Oct 2020 14:00'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473454

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'not specified'	(b) (4), (b) (6)	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '79'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473457

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'bpm'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '20'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473459

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473460

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '113'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473461

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'mmHg'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473462

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '73'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473463

US3492299
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'mmHg'	(b) (4), (b) (6) System	15 Oct 2020 00:30:02

FDA-CBER-2022-1614-2473464

US3492299
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:28:16

US3492299
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 00:28:16

FDA-CBER-2022-1614-2473466

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:15:23

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:15:23

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:15:23

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473471

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13:28'	(b) (4), (b) (6)	13 Oct 2020 19:15:23

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '13 Oct 2020 13:28'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473473

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Oct 2020 19:15:23

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'ONCE'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

US3492299
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

US3492299
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:32:19

US3492299
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:51
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 00:32:19

FDA-CBER-2022-1614-2473478

US3492299
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:51
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '13:05'	(b) (4), (b) (6)	15 Oct 2020 00:32:19

US3492299
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '13 Oct 2020 13:05'	(b) (4), (b) (6) System	15 Oct 2020 00:32:19

FDA-CBER-2022-1614-2473480

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:46:51
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:32:34

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:51
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Oct 2020 00:32:34

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:32:34

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:51
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '13:15'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:32:34

FDA-CBER-2022-1614-2473484

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '13 Oct 2020 13:15'	(b) (4), (b) (6) System	15 Oct 2020 00:32:34

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:51
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 00:32:34

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:32:34

FDA-CBER-2022-1614-2473487

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:51
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:32:34

US3492299
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered empty.	(b) (4), (b) (6) System	15 Oct 2020 00:32:34

US3492299
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:15:31

FDA-CBER-2022-1614-2473490

US3492299
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '1'	(b) (4), (b) (6) System	13 Oct 2020 19:15:31

FDA-CBER-2022-1614-2473491

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473492

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:15:46', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '2a6a4365-d35b-4cfc-875f-f9e221bcade3'	(b) (4), (b) (6) System	13 Oct 2020 19:16:17
User entered 'Yes (Y)'	System	13 Oct 2020 19:16:17

FDA-CBER-2022-1614-2473493

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:16:00', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '2a6a4365-d35b-4cfc-875f-f9e221bcade3'	(b) (4), (b) (6) System	13 Oct 2020 19:16:17
User entered '98.4'	System	13 Oct 2020 19:16:17

FDA-CBER-2022-1614-2473494

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:16:04', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '2a6a4365-d35b-4cfc-875f-f9e221bcade3'	(b) (4), (b) (6) System	13 Oct 2020 19:16:17
User entered 'No (N)'	System	13 Oct 2020 19:16:17

FDA-CBER-2022-1614-2473495

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:16:13', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '2a6a4365-d35b-4cfc-875f-f9e221bcade3'	(b) (4), (b) (6) System	13 Oct 2020 19:16:17
User entered '13 Oct 2020 14:16'	System	13 Oct 2020 19:16:17

FDA-CBER-2022-1614-2473496

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 13:48'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473497

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 16:18'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473498

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:06:30', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '29de4f53-5139-4560-9762-861eb6a01fa0'	System	14 Oct 2020 15:07:56
User entered 'Yes (Y)'	System	14 Oct 2020 15:07:56

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:07:45', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '29de4f53-5139-4560-9762-861eb6a01fa0'	(b) (4), (b) (6) System	14 Oct 2020 15:07:56
User entered '97.7'	System	14 Oct 2020 15:07:56

FDA-CBER-2022-1614-2473501

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:07:49', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '29de4f53-5139-4560-9762-861eb6a01fa0'	(b) (4), (b) (6) System	14 Oct 2020 15:07:56
User entered 'No (N)'	System	14 Oct 2020 15:07:56

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:07:55', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '29de4f53-5139-4560-9762-861eb6a01fa0'	(b) (4), (b) (6) System	14 Oct 2020 15:07:56
User entered '14 Oct 2020 10:07'	System	14 Oct 2020 15:07:56

FDA-CBER-2022-1614-2473503

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 17:13'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473504

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473505

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 2'	System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473506

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:14', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '19527cc8-24fa-43fe-934a-6e6879948af2'	(b) (4), (b) (6) System	14 Oct 2020 19:17:38
User entered 'Yes (Y)'	System	14 Oct 2020 19:17:38

FDA-CBER-2022-1614-2473507

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:24', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '19527cc8-24fa-43fe-934a-6e6879948af2'	(b) (4), (b) (6) System	14 Oct 2020 19:17:38
User entered '97.7'	System	14 Oct 2020 19:17:38

FDA-CBER-2022-1614-2473508

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:27', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '19527cc8-24fa-43fe-934a-6e6879948af2'	(b) (4), (b) (6) System	14 Oct 2020 19:17:38
User entered 'No (N)'	System	14 Oct 2020 19:17:38

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:35', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '19527cc8-24fa-43fe-934a-6e6879948af2'	(b) (4), (b) (6) System	14 Oct 2020 19:17:38
User entered '14 Oct 2020 14:17'	System	14 Oct 2020 19:17:38

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473511

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473512

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 3'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:16:52', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a9845908-256a-4376-94a2-b3eb3a20768e'	System	15 Oct 2020 20:17:10
User entered 'Yes (Y)'	System	15 Oct 2020 20:17:10

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:16:59', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a9845908-256a-4376-94a2-b3eb3a20768e'	(b) (4), (b) (6) System	15 Oct 2020 20:17:10
User entered '97.8'	System	15 Oct 2020 20:17:10

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:03', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a9845908-256a-4376-94a2-b3eb3a20768e'	(b) (4), (b) (6) System	15 Oct 2020 20:17:10
User entered 'No (N)'	System	15 Oct 2020 20:17:10

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:07', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a9845908-256a-4376-94a2-b3eb3a20768e'	(b) (4), (b) (6) System	15 Oct 2020 20:17:10
User entered '15 Oct 2020 15:17'	System	15 Oct 2020 20:17:10

FDA-CBER-2022-1614-2473517

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473518

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473519

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 4'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:03:45', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '2bb465ac-bd91-4fe9-9119-ca15e2200164'	System	16 Oct 2020 20:04:08
User entered 'Yes (Y)'	System	16 Oct 2020 20:04:08

FDA-CBER-2022-1614-2473521

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:03:52', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '2bb465ac-bd91-4fe9-9119-ca15e2200164'	(b) (4), (b) (6) System	16 Oct 2020 20:04:08
User entered '97.8'	System	16 Oct 2020 20:04:08

FDA-CBER-2022-1614-2473522

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:03:59', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '2bb465ac-bd91-4fe9-9119-ca15e2200164'	(b) (4), (b) (6) System	16 Oct 2020 20:04:08
User entered 'No (N)'	System	16 Oct 2020 20:04:08

FDA-CBER-2022-1614-2473523

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:01', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '2bb465ac-bd91-4fe9-9119-ca15e2200164'	(b) (4), (b) (6) System	16 Oct 2020 20:04:08
User entered '16 Oct 2020 15:04'	System	16 Oct 2020 20:04:08

FDA-CBER-2022-1614-2473524

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '16 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473525

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '17 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473526

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 5'	System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473527

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:06', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '8332ca7d-ce64-4430-83cc-407d33f60c54'	System	17 Oct 2020 17:40:23
User entered 'Yes (Y)'	System	17 Oct 2020 17:40:23

FDA-CBER-2022-1614-2473528

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:14', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '8332ca7d-ce64-4430-83cc-407d33f60c54'	(b) (4), (b) (6) System	17 Oct 2020 17:40:23
User entered '98.5'	System	17 Oct 2020 17:40:23

FDA-CBER-2022-1614-2473529

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:17', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '8332ca7d-ce64-4430-83cc-407d33f60c54'	(b) (4), (b) (6) System	17 Oct 2020 17:40:23
User entered 'No (N)'	System	17 Oct 2020 17:40:23

FDA-CBER-2022-1614-2473530

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:20', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '8332ca7d-ce64-4430-83cc-407d33f60c54'	(b) (4), (b) (6) System	17 Oct 2020 17:40:23
User entered '17 Oct 2020 12:40'	System	17 Oct 2020 17:40:23

FDA-CBER-2022-1614-2473531

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '17 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473532

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '18 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473533

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 6'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:02', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fdb13e54-c937-4a2a-8fd1-10697d5465cc'	(b) (4), (b) (6) System	18 Oct 2020 22:33:20
User entered 'Yes (Y)'	System	18 Oct 2020 22:33:20

FDA-CBER-2022-1614-2473535

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:11', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fdb13e54-c937-4a2a-8fd1-10697d5465cc'	(b) (4), (b) (6) System	18 Oct 2020 22:33:20
User entered '96.4'	System	18 Oct 2020 22:33:20

FDA-CBER-2022-1614-2473536

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:15', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fdb13e54-c937-4a2a-8fd1-10697d5465cc'	(b) (4), (b) (6) System	18 Oct 2020 22:33:20
User entered 'No (N)'	System	18 Oct 2020 22:33:20

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:17', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fdb13e54-c937-4a2a-8fd1-10697d5465cc'	(b) (4), (b) (6) System	18 Oct 2020 22:33:20
User entered '18 Oct 2020 17:33'	System	18 Oct 2020 22:33:20

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '18 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473539

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '19 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473540

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 7'	System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473541

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:00:47', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b3be2a75-b564-4df0-be82-ca3874b56b6f'	(b) (4), (b) (6) System	19 Oct 2020 16:01:50
User entered 'Yes (Y)'	System	19 Oct 2020 16:01:50

FDA-CBER-2022-1614-2473542

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:00:58', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b3be2a75-b564-4df0-be82-ca3874b56b6f'	(b) (4), (b) (6) System	19 Oct 2020 16:01:50
User entered '97.6'	System	19 Oct 2020 16:01:50

FDA-CBER-2022-1614-2473543

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:00', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b3be2a75-b564-4df0-be82-ca3874b56b6f'	(b) (4), (b) (6) System	19 Oct 2020 16:01:50
User entered 'No (N)'	System	19 Oct 2020 16:01:50

FDA-CBER-2022-1614-2473544

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:03', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b3be2a75-b564-4df0-be82-ca3874b56b6f'	(b) (4), (b) (6) System	19 Oct 2020 16:01:50
User entered '19 Oct 2020 12:01'	System	19 Oct 2020 16:01:50

FDA-CBER-2022-1614-2473545

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '19 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473546

US3492299
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '20 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473547

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:16:30', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e272860-1d9c-4657-bec2-72ae4c44e41f'	System	13 Oct 2020 19:17:16
User entered 'None (1)'	System	13 Oct 2020 19:17:16

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:16:34', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e272860-1d9c-4657-bec2-72ae4c44e41f'	(b) (4), (b) (6) System	13 Oct 2020 19:17:16
User entered 'No (N)'	System	13 Oct 2020 19:17:16

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:16:52', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e272860-1d9c-4657-bec2-72ae4c44e41f'	System	13 Oct 2020 19:17:16
User entered 'No (N)'	System	13 Oct 2020 19:17:16

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:09', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e272860-1d9c-4657-bec2-72ae4c44e41f'	System	13 Oct 2020 19:17:16
User entered 'None (1)'	System	13 Oct 2020 19:17:16

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:12', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e272860-1d9c-4657-bec2-72ae4c44e41f'	(b) (4), (b) (6) System	13 Oct 2020 19:17:16
User entered '13 Oct 2020 14:17'	System	13 Oct 2020 19:17:16

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 13:48'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 16:18'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:05', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'c20bef8e-3cb8-40a1-b2a9-1349817f31ff'	System	14 Oct 2020 15:08:23
User entered 'None (1)'	System	14 Oct 2020 15:08:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'c20bef8e-3cb8-40a1-b2a9-1349817f31ff'	(b) (4), (b) (6) System	14 Oct 2020 15:08:23
User entered 'No (N)'	System	14 Oct 2020 15:08:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:12', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'c20bef8e-3cb8-40a1-b2a9-1349817f31ff'	(b) (4), (b) (6) System	14 Oct 2020 15:08:23
User entered 'No (N)'	System	14 Oct 2020 15:08:23

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:17', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'c20bef8e-3cb8-40a1-b2a9-1349817f31ff'	System	14 Oct 2020 15:08:23
User entered 'None (1)'	System	14 Oct 2020 15:08:23

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:20', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'c20bef8e-3cb8-40a1-b2a9-1349817f31ff'	(b) (4), (b) (6) System	14 Oct 2020 15:08:23
User entered '14 Oct 2020 10:08'	System	14 Oct 2020 15:08:23

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 17:13'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473562

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 2'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:40', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '6ae9146e-4a93-40bf-b60b-ce61dad8e9ea'	System	14 Oct 2020 19:18:00
User entered 'None (1)'	System	14 Oct 2020 19:18:00

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:43', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '6ae9146e-4a93-40bf-b60b-ce61dad8e9ea'	(b) (4), (b) (6) System	14 Oct 2020 19:18:00
User entered 'No (N)'	System	14 Oct 2020 19:18:00

FDA-CBER-2022-1614-2473566

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:48', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '6ae9146e-4a93-40bf-b60b-ce61dad8e9ea'	System	14 Oct 2020 19:18:00
User entered 'No (N)'	System	14 Oct 2020 19:18:00

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:51', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '6ae9146e-4a93-40bf-b60b-ce61dad8e9ea'	System	14 Oct 2020 19:18:00
User entered 'None (1)'	System	14 Oct 2020 19:18:00

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:54', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '6ae9146e-4a93-40bf-b60b-ce61dad8e9ea'	(b) (4), (b) (6) System	14 Oct 2020 19:18:00
User entered '14 Oct 2020 14:17'	System	14 Oct 2020 19:18:00

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 3'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:11', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'abf89c09-6db4-4337-a703-c3de92635086'	System	15 Oct 2020 20:17:31
User entered 'None (1)'	System	15 Oct 2020 20:17:31

FDA-CBER-2022-1614-2473573

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:14', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'abf89c09-6db4-4337-a703-c3de92635086'	System	15 Oct 2020 20:17:31
User entered 'No (N)'	System	15 Oct 2020 20:17:31

FDA-CBER-2022-1614-2473574

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:20', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'abf89c09-6db4-4337-a703-c3de92635086'	(b) (4), (b) (6) System	15 Oct 2020 20:17:31
User entered 'No (N)'	System	15 Oct 2020 20:17:31

FDA-CBER-2022-1614-2473575

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:25', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'abf89c09-6db4-4337-a703-c3de92635086'	System	15 Oct 2020 20:17:31
User entered 'None (1)'	System	15 Oct 2020 20:17:31

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US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:28', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'abf89c09-6db4-4337-a703-c3de92635086'	(b) (4), (b) (6) System	15 Oct 2020 20:17:31
User entered '15 Oct 2020 15:17'	System	15 Oct 2020 20:17:31

FDA-CBER-2022-1614-2473577

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473578

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473579

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 4'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:07', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '50f43205-03ea-44cc-b1ed-cd37bd0f5322'	System	16 Oct 2020 20:04:25
User entered 'None (1)'	System	16 Oct 2020 20:04:25

FDA-CBER-2022-1614-2473581

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:11', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '50f43205-03ea-44cc-b1ed-cd37bd0f5322'	(b) (4), (b) (6) System	16 Oct 2020 20:04:25
User entered 'No (N)'	System	16 Oct 2020 20:04:25

FDA-CBER-2022-1614-2473582

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:17', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '50f43205-03ea-44cc-b1ed-cd37bd0f5322'	(b) (4), (b) (6) System	16 Oct 2020 20:04:25
User entered 'No (N)'	System	16 Oct 2020 20:04:25

FDA-CBER-2022-1614-2473583

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:20', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '50f43205-03ea-44cc-b1ed-cd37bd0f5322'	System	16 Oct 2020 20:04:25
User entered 'None (1)'	System	16 Oct 2020 20:04:25

FDA-CBER-2022-1614-2473584

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:22', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '50f43205-03ea-44cc-b1ed-cd37bd0f5322'	(b) (4), (b) (6) System	16 Oct 2020 20:04:25
User entered '16 Oct 2020 15:04'	System	16 Oct 2020 20:04:25

FDA-CBER-2022-1614-2473585

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '16 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473586

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '17 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473587

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 5'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:26', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fbb7d574-2cb8-401b-b52d-7ccbe431cf7d'	System	17 Oct 2020 17:40:39
User entered 'None (1)'	System	17 Oct 2020 17:40:39

FDA-CBER-2022-1614-2473589

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:30', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fbb7d574-2cb8-401b-b52d-7ccbe431cf7d'	(b) (4), (b) (6) System	17 Oct 2020 17:40:39
User entered 'No (N)'	System	17 Oct 2020 17:40:39

FDA-CBER-2022-1614-2473590

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:33', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fbb7d574-2cb8-401b-b52d-7ccbe431cf7d'	(b) (4), (b) (6) System	17 Oct 2020 17:40:39
User entered 'No (N)'	System	17 Oct 2020 17:40:39

FDA-CBER-2022-1614-2473591

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:35', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fbb7d574-2cb8-401b-b52d-7ccbe431cf7d'	System	17 Oct 2020 17:40:39
User entered 'None (1)'	System	17 Oct 2020 17:40:39

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:37', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'fbb7d574-2cb8-401b-b52d-7ccbe431cf7d'	(b) (4), (b) (6) System	17 Oct 2020 17:40:39
User entered '17 Oct 2020 12:40'	System	17 Oct 2020 17:40:39

FDA-CBER-2022-1614-2473593

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '17 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473594

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '18 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473595

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 6'	System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473596

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:21', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '02a5fe91-7ba4-4f87-89dd-df0e10a53e11'	System	18 Oct 2020 22:33:33
User entered 'None (1)'	System	18 Oct 2020 22:33:33

FDA-CBER-2022-1614-2473597

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:23', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '02a5fe91-7ba4-4f87-89dd-df0e10a53e11'	(b) (4), (b) (6) System	18 Oct 2020 22:33:33
User entered 'No (N)'	System	18 Oct 2020 22:33:33

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:25', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '02a5fe91-7ba4-4f87-89dd-df0e10a53e11'	(b) (4), (b) (6) System	18 Oct 2020 22:33:33
User entered 'No (N)'	System	18 Oct 2020 22:33:33

FDA-CBER-2022-1614-2473599

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:27', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '02a5fe91-7ba4-4f87-89dd-df0e10a53e11'	System	18 Oct 2020 22:33:33
User entered 'None (1)'	System	18 Oct 2020 22:33:33

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:29', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '02a5fe91-7ba4-4f87-89dd-df0e10a53e11'	(b) (4), (b) (6) System	18 Oct 2020 22:33:33
User entered '18 Oct 2020 17:33'	System	18 Oct 2020 22:33:33

FDA-CBER-2022-1614-2473601

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '18 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473602

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '19 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473603

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 7'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:07', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'f25b627f-340f-46b6-b31e-1798e600593d'	System	19 Oct 2020 16:02:12
User entered 'None (1)'	System	19 Oct 2020 16:02:12

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:10', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'f25b627f-340f-46b6-b31e-1798e600593d'	System	19 Oct 2020 16:02:12
User entered 'No (N)'	System	19 Oct 2020 16:02:12

FDA-CBER-2022-1614-2473606

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:12', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'f25b627f-340f-46b6-b31e-1798e600593d'	System	19 Oct 2020 16:02:12
User entered 'No (N)'	System	19 Oct 2020 16:02:12

FDA-CBER-2022-1614-2473607

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:13', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'f25b627f-340f-46b6-b31e-1798e600593d'	System	19 Oct 2020 16:02:12
User entered 'None (1)'	System	19 Oct 2020 16:02:12

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:16', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'f25b627f-340f-46b6-b31e-1798e600593d'	(b) (4), (b) (6) System	19 Oct 2020 16:02:12
User entered '19 Oct 2020 12:01'	System	19 Oct 2020 16:02:12

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '19 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '20 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473611

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:18', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a5a79562-6537-41eb-88c5-1bc7889ff49d'	(b) (4), (b) (6) System	13 Oct 2020 19:17:58
User entered 'None (0)'	System	13 Oct 2020 19:17:58

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:24', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a5a79562-6537-41eb-88c5-1bc7889ff49d'	(b) (4), (b) (6) System	13 Oct 2020 19:17:58
User entered 'None (0)'	System	13 Oct 2020 19:17:58

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:32', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a5a79562-6537-41eb-88c5-1bc7889ff49d'	(b) (4), (b) (6) System	13 Oct 2020 19:17:58
User entered 'None (0)'	System	13 Oct 2020 19:17:58

FDA-CBER-2022-1614-2473615

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:36', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a5a79562-6537-41eb-88c5-1bc7889ff49d'	(b) (4), (b) (6) System	13 Oct 2020 19:17:58
User entered 'None (0)'	System	13 Oct 2020 19:17:58

FDA-CBER-2022-1614-2473616

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:42', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a5a79562-6537-41eb-88c5-1bc7889ff49d'	(b) (4), (b) (6) System	13 Oct 2020 19:17:58
User entered 'None (0)'	System	13 Oct 2020 19:17:58

FDA-CBER-2022-1614-2473617

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:48', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a5a79562-6537-41eb-88c5-1bc7889ff49d'	(b) (4), (b) (6) System	13 Oct 2020 19:17:58
User entered 'None (0)'	System	13 Oct 2020 19:17:58

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
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)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:53', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a5a79562-6537-41eb-88c5-1bc7889ff49d'	(b) (4), (b) (6) System	13 Oct 2020 19:17:58
User entered 'No (N)'	System	13 Oct 2020 19:17:58

FDA-CBER-2022-1614-2473619

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-13T14:17:55', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a5a79562-6537-41eb-88c5-1bc7889ff49d'	System	13 Oct 2020 19:17:58
User entered '13 Oct 2020 14:17'	System	13 Oct 2020 19:17:58

FDA-CBER-2022-1614-2473620

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 13:48'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473621

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 16:18'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473622

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:25', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '595051ee-df4b-4c0b-9ecb-8a1b71dcc5b5'	(b) (4), (b) (6) System	14 Oct 2020 15:08:45
User entered 'None (0)'	System	14 Oct 2020 15:08:45

FDA-CBER-2022-1614-2473624

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:27', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '595051ee-df4b-4c0b-9ecb-8a1b71dcc5b5'	(b) (4), (b) (6) System	14 Oct 2020 15:08:45
User entered 'None (0)'	System	14 Oct 2020 15:08:45

FDA-CBER-2022-1614-2473625

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:29', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '595051ee-df4b-4c0b-9ecb-8a1b71dcc5b5'	(b) (4), (b) (6) System	14 Oct 2020 15:08:45
User entered 'None (0)'	System	14 Oct 2020 15:08:45

FDA-CBER-2022-1614-2473626

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:31', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '595051ee-df4b-4c0b-9ecb-8a1b71dcc5b5'	(b) (4), (b) (6) System	14 Oct 2020 15:08:45
User entered 'None (0)'	System	14 Oct 2020 15:08:45

FDA-CBER-2022-1614-2473627

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:33', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '595051ee-df4b-4c0b-9ecb-8a1b71dcc5b5'	(b) (4), (b) (6) System	14 Oct 2020 15:08:45
User entered 'None (0)'	System	14 Oct 2020 15:08:45

FDA-CBER-2022-1614-2473628

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:35', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '595051ee-df4b-4c0b-9ecb-8a1b71dcc5b5'	(b) (4), (b) (6) System	14 Oct 2020 15:08:45
User entered 'None (0)'	System	14 Oct 2020 15:08:45

FDA-CBER-2022-1614-2473629

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
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)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:39', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '595051ee-df4b-4c0b-9ecb-8a1b71dcc5b5'	(b) (4), (b) (6) System	14 Oct 2020 15:08:45
User entered 'No (N)'	System	14 Oct 2020 15:08:45

FDA-CBER-2022-1614-2473630

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T10:08:42', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '595051ee-df4b-4c0b-9ecb-8a1b71dcc5b5'	(b) (4), (b) (6) System	14 Oct 2020 15:08:45
User entered '14 Oct 2020 10:08'	System	14 Oct 2020 15:08:45

FDA-CBER-2022-1614-2473631

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '13 Oct 2020 17:13'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473632

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '14 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473633

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 2'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:17:58', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e5a5e9e-5266-4999-98ba-dc45a1345026'	System	14 Oct 2020 19:18:20
User entered 'None (0)'	System	14 Oct 2020 19:18:20

FDA-CBER-2022-1614-2473635

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:18:00', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e5a5e9e-5266-4999-98ba-dc45a1345026'	(b) (4), (b) (6) System	14 Oct 2020 19:18:20
User entered 'None (0)'	System	14 Oct 2020 19:18:20

FDA-CBER-2022-1614-2473636

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:18:02', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e5a5e9e-5266-4999-98ba-dc45a1345026'	(b) (4), (b) (6) System	14 Oct 2020 19:18:20
User entered 'None (0)'	System	14 Oct 2020 19:18:20

FDA-CBER-2022-1614-2473637

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:18:03', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e5a5e9e-5266-4999-98ba-dc45a1345026'	(b) (4), (b) (6) System	14 Oct 2020 19:18:20
User entered 'None (0)'	System	14 Oct 2020 19:18:20

FDA-CBER-2022-1614-2473638

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:18:07', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e5a5e9e-5266-4999-98ba-dc45a1345026'	System	14 Oct 2020 19:18:20
User entered 'None (0)'	System	14 Oct 2020 19:18:20

FDA-CBER-2022-1614-2473639

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:18:09', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e5a5e9e-5266-4999-98ba-dc45a1345026'	(b) (4), (b) (6) System	14 Oct 2020 19:18:20
User entered 'None (0)'	System	14 Oct 2020 19:18:20

FDA-CBER-2022-1614-2473640

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
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)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:18:14', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e5a5e9e-5266-4999-98ba-dc45a1345026'	(b) (4), (b) (6) System	14 Oct 2020 19:18:20
User entered 'No (N)'	System	14 Oct 2020 19:18:20

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-14T14:18:17', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '0e5a5e9e-5266-4999-98ba-dc45a1345026'	(b) (4), (b) (6) System	14 Oct 2020 19:18:20
User entered '14 Oct 2020 14:18'	System	14 Oct 2020 19:18:20

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '14 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473643

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '15 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 3'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:32', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9d2fa3a5-d447-4f7c-8124-7cb752eec1c8'	(b) (4), (b) (6) System	15 Oct 2020 20:17:53
User entered 'None (0)'	System	15 Oct 2020 20:17:53

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:34', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9d2fa3a5-d447-4f7c-8124-7cb752eec1c8'	(b) (4), (b) (6) System	15 Oct 2020 20:17:53
User entered 'None (0)'	System	15 Oct 2020 20:17:53

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:37', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9d2fa3a5-d447-4f7c-8124-7cb752eec1c8'	(b) (4), (b) (6) System	15 Oct 2020 20:17:53
User entered 'None (0)'	System	15 Oct 2020 20:17:53

FDA-CBER-2022-1614-2473648

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:39', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9d2fa3a5-d447-4f7c-8124-7cb752eec1c8'	(b) (4), (b) (6) System	15 Oct 2020 20:17:53
User entered 'None (0)'	System	15 Oct 2020 20:17:53

FDA-CBER-2022-1614-2473649

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:41', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9d2fa3a5-d447-4f7c-8124-7cb752eec1c8'	System	15 Oct 2020 20:17:53
User entered 'None (0)'	System	15 Oct 2020 20:17:53

FDA-CBER-2022-1614-2473650

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:43', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9d2fa3a5-d447-4f7c-8124-7cb752eec1c8'	(b) (4), (b) (6) System	15 Oct 2020 20:17:53
User entered 'None (0)'	System	15 Oct 2020 20:17:53

FDA-CBER-2022-1614-2473651

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
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)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:47', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9d2fa3a5-d447-4f7c-8124-7cb752eec1c8'	(b) (4), (b) (6) System	15 Oct 2020 20:17:53
User entered 'No (N)'	System	15 Oct 2020 20:17:53

FDA-CBER-2022-1614-2473652

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-15T15:17:49', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9d2fa3a5-d447-4f7c-8124-7cb752eec1c8'	System	15 Oct 2020 20:17:53
User entered '15 Oct 2020 15:17'	System	15 Oct 2020 20:17:53

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '15 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473654

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '16 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473655

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 4'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:26', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '044eabe1-d27f-47c9-8a11-d4778fe91a07'	(b) (4), (b) (6) System	16 Oct 2020 20:04:45
User entered 'None (0)'	System	16 Oct 2020 20:04:45

FDA-CBER-2022-1614-2473657

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:28', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '044eabe1-d27f-47c9-8a11-d4778fe91a07'	(b) (4), (b) (6) System	16 Oct 2020 20:04:45
User entered 'None (0)'	System	16 Oct 2020 20:04:45

FDA-CBER-2022-1614-2473658

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:30', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '044eabe1-d27f-47c9-8a11-d4778fe91a07'	(b) (4), (b) (6) System	16 Oct 2020 20:04:45
User entered 'None (0)'	System	16 Oct 2020 20:04:45

FDA-CBER-2022-1614-2473659

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:32', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '044eabe1-d27f-47c9-8a11-d4778fe91a07'	(b) (4), (b) (6) System	16 Oct 2020 20:04:45
User entered 'None (0)'	System	16 Oct 2020 20:04:45

FDA-CBER-2022-1614-2473660

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:34', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '044eabe1-d27f-47c9-8a11-d4778fe91a07'	(b) (4), (b) (6) System	16 Oct 2020 20:04:45
User entered 'None (0)'	System	16 Oct 2020 20:04:45

FDA-CBER-2022-1614-2473661

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:37', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '044eabe1-d27f-47c9-8a11-d4778fe91a07'	(b) (4), (b) (6) System	16 Oct 2020 20:04:45
User entered 'None (0)'	System	16 Oct 2020 20:04:45

FDA-CBER-2022-1614-2473662

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
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)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:39', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '044eabe1-d27f-47c9-8a11-d4778fe91a07'	(b) (4), (b) (6) System	16 Oct 2020 20:04:45
User entered 'No (N)'	System	16 Oct 2020 20:04:45

FDA-CBER-2022-1614-2473663

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-16T15:04:42', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '044eabe1-d27f-47c9-8a11-d4778fe91a07'	System	16 Oct 2020 20:04:45
User entered '16 Oct 2020 15:04'	System	16 Oct 2020 20:04:45

FDA-CBER-2022-1614-2473664

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '16 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473665

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '17 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473666

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 5'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:43', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b61ea298-5521-4edf-961d-2a195356cad5'	(b) (4), (b) (6) System	17 Oct 2020 17:41:00
User entered 'None (0)'	System	17 Oct 2020 17:41:00

FDA-CBER-2022-1614-2473668

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:45', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b61ea298-5521-4edf-961d-2a195356cad5'	(b) (4), (b) (6) System	17 Oct 2020 17:41:00
User entered 'None (0)'	System	17 Oct 2020 17:41:00

FDA-CBER-2022-1614-2473669

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:47', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b61ea298-5521-4edf-961d-2a195356cad5'	(b) (4), (b) (6) System	17 Oct 2020 17:41:00
User entered 'None (0)'	System	17 Oct 2020 17:41:00

FDA-CBER-2022-1614-2473670

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:49', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b61ea298-5521-4edf-961d-2a195356cad5'	(b) (4), (b) (6) System	17 Oct 2020 17:41:00
User entered 'None (0)'	System	17 Oct 2020 17:41:00

FDA-CBER-2022-1614-2473671

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:51', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b61ea298-5521-4edf-961d-2a195356cad5'	(b) (4), (b) (6) System	17 Oct 2020 17:41:00
User entered 'None (0)'	System	17 Oct 2020 17:41:00

FDA-CBER-2022-1614-2473672

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:53', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b61ea298-5521-4edf-961d-2a195356cad5'	System	17 Oct 2020 17:41:00
User entered 'None (0)'	System	17 Oct 2020 17:41:00

FDA-CBER-2022-1614-2473673

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
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)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:56', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b61ea298-5521-4edf-961d-2a195356cad5'	(b) (4), (b) (6) System	17 Oct 2020 17:41:00
User entered 'No (N)'	System	17 Oct 2020 17:41:00

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-17T12:40:58', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'b61ea298-5521-4edf-961d-2a195356cad5'	(b) (4), (b) (6) System	17 Oct 2020 17:41:00
User entered '17 Oct 2020 12:40'	System	17 Oct 2020 17:41:00

FDA-CBER-2022-1614-2473675

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '17 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '18 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473677

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	(b) (4), (b) (6) System	13 Oct 2020 19:15:23
User entered 'Day 6'	System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473678

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:35', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '32430752-ace7-4ac5-af50-713ab84cf9bb'	(b) (4), (b) (6) System	18 Oct 2020 22:34:00
User entered 'None (0)'	System	18 Oct 2020 22:34:00

FDA-CBER-2022-1614-2473679

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:45', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '32430752-ace7-4ac5-af50-713ab84cf9bb'	(b) (4), (b) (6) System	18 Oct 2020 22:34:00
User entered 'None (0)'	System	18 Oct 2020 22:34:00

FDA-CBER-2022-1614-2473680

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:47', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '32430752-ace7-4ac5-af50-713ab84cf9bb'	(b) (4), (b) (6) System	18 Oct 2020 22:34:00
User entered 'None (0)'	System	18 Oct 2020 22:34:00

FDA-CBER-2022-1614-2473681

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:49', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '32430752-ace7-4ac5-af50-713ab84cf9bb'	(b) (4), (b) (6) System	18 Oct 2020 22:34:00
User entered 'None (0)'	System	18 Oct 2020 22:34:00

FDA-CBER-2022-1614-2473682

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:50', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '32430752-ace7-4ac5-af50-713ab84cf9bb'	(b) (4), (b) (6) System	18 Oct 2020 22:34:00
User entered 'None (0)'	System	18 Oct 2020 22:34:00

FDA-CBER-2022-1614-2473683

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:52', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '32430752-ace7-4ac5-af50-713ab84cf9bb'	(b) (4), (b) (6) System	18 Oct 2020 22:34:00
User entered 'None (0)'	System	18 Oct 2020 22:34:00

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
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)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:55', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '32430752-ace7-4ac5-af50-713ab84cf9bb'	(b) (4), (b) (6) System	18 Oct 2020 22:34:00
User entered 'No (N)'	System	18 Oct 2020 22:34:00

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-18T17:33:57', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '32430752-ace7-4ac5-af50-713ab84cf9bb'	System	18 Oct 2020 22:34:00
User entered '18 Oct 2020 17:33'	System	18 Oct 2020 22:34:00

FDA-CBER-2022-1614-2473686

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '18 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473687

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '19 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473688

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
Data entry locked.	System	13 Oct 2020 19:15:23
User entered 'Day 7'	System	13 Oct 2020 19:15:23

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:20', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9c555ad4-f637-4494-bd4a-ab48b193e0ed'	(b) (4), (b) (6) System	19 Oct 2020 16:02:38
User entered 'None (0)'	System	19 Oct 2020 16:02:38

FDA-CBER-2022-1614-2473690

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:22', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9c555ad4-f637-4494-bd4a-ab48b193e0ed'	(b) (4), (b) (6) System	19 Oct 2020 16:02:38
User entered 'None (0)'	System	19 Oct 2020 16:02:38

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:24', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9c555ad4-f637-4494-bd4a-ab48b193e0ed'	(b) (4), (b) (6) System	19 Oct 2020 16:02:38
User entered 'None (0)'	System	19 Oct 2020 16:02:38

FDA-CBER-2022-1614-2473692

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:25', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9c555ad4-f637-4494-bd4a-ab48b193e0ed'	(b) (4), (b) (6) System	19 Oct 2020 16:02:38
User entered 'None (0)'	System	19 Oct 2020 16:02:38

FDA-CBER-2022-1614-2473693

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:27', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9c555ad4-f637-4494-bd4a-ab48b193e0ed'	(b) (4), (b) (6) System	19 Oct 2020 16:02:38
User entered 'None (0)'	System	19 Oct 2020 16:02:38

FDA-CBER-2022-1614-2473694

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:29', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9c555ad4-f637-4494-bd4a-ab48b193e0ed'	(b) (4), (b) (6) System	19 Oct 2020 16:02:38
User entered 'None (0)'	System	19 Oct 2020 16:02:38

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
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)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:31', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9c555ad4-f637-4494-bd4a-ab48b193e0ed'	(b) (4), (b) (6) System	19 Oct 2020 16:02:38
User entered 'No (N)'	System	19 Oct 2020 16:02:38

FDA-CBER-2022-1614-2473696

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	25 Feb 2021 23:06:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-10-19T12:01:33', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '9c555ad4-f637-4494-bd4a-ab48b193e0ed'	System	19 Oct 2020 16:02:38
User entered '19 Oct 2020 12:01'	System	19 Oct 2020 16:02:38

FDA-CBER-2022-1614-2473697

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '19 Oct 2020 12:00'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473698

US3492299
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:06:14
User entered '20 Oct 2020 11:59'	(b) (4), (b) (6) System	13 Oct 2020 19:15:23

FDA-CBER-2022-1614-2473699

US3492299
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:38:45

US3492299
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered '20 Oct 2020'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:38:45

US3492299
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	26 Apr 2021 16:36:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Andrea Wendrow (b) (4)	30 Mar 2021 20:38:45

US3492299
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'multiple attempts, restrictions on phone from carrier'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:38:45

FDA-CBER-2022-1614-2473703

US3492299
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:58:29

US3492299
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '1'	(b) (4), (b) (6) System	02 Nov 2020 19:58:29

US3492299
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:59:48

US3492299
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '30 Oct 2020'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:59:48

US3492299
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:59:48

US3492299
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'three call attempts made. alternate contact did not answer call, voicemail left.'	Lorna Sanchez McCann (b) (4)	02 Nov 2020 19:59:48

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US3492299
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:08:51

US3492299
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '1'	(b) (4), (b) (6) System	05 Nov 2020 15:08:51

US3492299
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:09:10

US3492299
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 15:09:10

US3492299
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 15:09:10

US3492299
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:09:10

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US3492299
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 15:09:40

FDA-CBER-2022-1614-2473716

US3492299
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:59
User entered '1'	(b) (4), (b) (6) System	05 Nov 2020 15:09:40

FDA-CBER-2022-1614-2473717

US3492299
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per CDM: Please complete 'exposure' form under visit 2 folder.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 07:27:31
Query 'Per CDM: Please complete 'exposure' form under visit 2 folder.' answered with 'completed' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	29 Jan 2021 22:33:14
User opened query 'Per CDM: Please complete 'exposure' form under visit 2 folder.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 12:49:13
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:58

US3492299
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:58

US3492299
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:58

US3492299
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:45:43
User entered 'VISIT2'	(b) (4), (b) (6) System	18 Nov 2020 15:25:58

FDA-CBER-2022-1614-2473721

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 16:11:04

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	29 Jan 2021 22:31:44
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	29 Jan 2021 22:31:44
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	29 Jan 2021 16:11:04
User entered empty.	Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 16:11:04

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
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) (b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 16:11:04

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:45:43
User entered empty.	(b) (4), (b) (6) System	29 Jan 2021 16:11:04

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 16:11:04

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US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 16:11:04

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:45:43
User entered empty.	(b) (4), (b) (6) System	29 Jan 2021 16:11:04

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US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Marla Schwarber (b) (4) (b) (4)	29 Jan 2021 16:11:04

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:45:43
User entered empty.	(b) (4), (b) (6) System	29 Jan 2021 16:11:04

US3492299
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:51
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:45:43
User entered empty.	(b) (4), (b) (6) System	29 Jan 2021 16:11:04

US3492299
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 07:45:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:09

US3492299
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:45:43
User entered '1'	(b) (4), (b) (6) System	18 Nov 2020 15:25:09

FDA-CBER-2022-1614-2473733

US3492299
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:20

US3492299
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '17 Nov 2020'	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:20

US3492299
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:20

FDA-CBER-2022-1614-2473736

US3492299
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:20

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US3492299
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	18 Nov 2020 15:25:31

US3492299
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered '1'	(b) (4), (b) (6) System	18 Nov 2020 15:25:31

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US3492299
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:36:42

US3492299
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:36:42

US3492299
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:36:42

FDA-CBER-2022-1614-2473742

US3492299
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'subject MIA'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:36:42

FDA-CBER-2022-1614-2473743

US3492299
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	31 Mar 2021 19:29:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	31 Mar 2021 19:29:09
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:57:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Mar 2021 12:25:17
Query 'Data is required. Please complete.' answered with 'not required, visit not completed' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	10 Mar 2021 17:23:48
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 17:23:34
Signature has been broken.	Andrea Wendrow (b) (4) (b) (4)	10 Mar 2021 17:23:34
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	10 Mar 2021 17:23:34
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 17:15:29

FDA-CBER-2022-1614-2473744

US3492299
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered '1'	System	31 Mar 2021 19:29:09
User entered empty.	System	10 Mar 2021 17:23:34
User entered '1'	System	11 Jan 2021 17:15:29

US3492299
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	31 Mar 2021 19:33:09

US3492299
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	31 Mar 2021 19:33:09

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US3492299
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	31 Mar 2021 19:33:09

US3492299
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	(b) (4), (b) (6) Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'subject MIA despite multiple contact attempts thought MIA period'	Andrea Wendrow (b) (4) (b) (4)	31 Mar 2021 19:33:09

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US3492299
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
Signature has been broken.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:40:30
User entered 'Yes (Y)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:40:30
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:57:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Mar 2021 12:25:27
Query 'Data is required. Please complete.' answered with 'not required, visit not completed' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	10 Mar 2021 17:23:17
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 17:22:52
Signature has been broken.	Andrea Wendrow (b) (4) (b) (4)	10 Mar 2021 17:22:52
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	10 Mar 2021 17:22:52
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 17:16:25

US3492299
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered '1'	System	30 Mar 2021 20:40:30
User entered empty.	System	10 Mar 2021 17:22:52
User entered '1'	System	11 Jan 2021 17:16:25

US3492299
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:40:54

US3492299
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:40:54

US3492299
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:40:54

US3492299
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered 'VISIT3'	(b) (4), (b) (6) System	30 Mar 2021 20:40:54

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US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:44:24

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US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:44:24

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US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:44:24

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US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:44:24

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US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:24

US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 20:44:24

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US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13

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US3492299
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13

FDA-CBER-2022-1614-2473772

US3492299
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:33

US3492299
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:33

US3492299
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:39

US3492299
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:51
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:39

US3492299
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:51
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:44:39

US3492299
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered empty.	System	30 Mar 2021 20:44:39

US3492299
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:41:32

FDA-CBER-2022-1614-2473779

US3492299
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 11:53:13
User entered '1'	System	30 Mar 2021 20:41:32

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:29:05

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:52:20', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered 'Yes (Y)'	System	10 Dec 2020 12:53:44

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:52:25', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered 'Yes (Y)'	System	10 Dec 2020 12:53:44

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Please 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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:52:37', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 12:53:44

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:52:44', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered 'Yes (Y)'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '1'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '1'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '1'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '1'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '1'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '0'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:08', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '1'	System	10 Dec 2020 12:53:44

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Please 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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:13', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 12:53:44

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:19', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered 'Yes (Y)'	System	10 Dec 2020 12:53:44

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Please 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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:23', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-10T07:53:33', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd144dc93-0285-4292-a3e1-c610ad0b45e8'	System	10 Dec 2020 12:53:44
User entered '10 Dec 2020 07:53:33'	System	10 Dec 2020 12:53:44

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:29:05

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-17T06:37:48', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '65ab021b-8770-455f-9113-b3f951b8b538'	System	17 Dec 2020 11:38:03
User entered 'No (N)'	System	17 Dec 2020 11:38:03

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-17T06:37:57', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '65ab021b-8770-455f-9113-b3f951b8b538'	System	17 Dec 2020 11:38:03
User entered 'No (N)'	System	17 Dec 2020 11:38:03

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-17T06:38:01', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '65ab021b-8770-455f-9113-b3f951b8b538'	System	17 Dec 2020 11:38:03
User entered '17 Dec 2020 06:38:01'	System	17 Dec 2020 11:38:03

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:29:05

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-24T09:47:20', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a99f88e4-5648-4c6b-82fe-15e8c61a07f0'	System	24 Dec 2020 14:47:31
User entered 'No (N)'	System	24 Dec 2020 14:47:31

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-24T09:47:26', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a99f88e4-5648-4c6b-82fe-15e8c61a07f0'	System	24 Dec 2020 14:47:31
User entered 'No (N)'	System	24 Dec 2020 14:47:31

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2020-12-24T09:47:30', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'a99f88e4-5648-4c6b-82fe-15e8c61a07f0'	System	24 Dec 2020 14:47:31
User entered '24 Dec 2020 09:47:30'	System	24 Dec 2020 14:47:31

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:29:05

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Please 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) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2473841

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2473842

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Please 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) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Please 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) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:29:05

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2021-01-10T18:26:25', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '20db1b12-d458-47cd-b34b-65e9f307e209'	System	15 Jan 2021 21:57:18
User entered 'No (N)'	System	15 Jan 2021 21:57:18

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2021-01-10T18:26:31', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '20db1b12-d458-47cd-b34b-65e9f307e209'	System	15 Jan 2021 21:57:18
User entered 'No (N)'	System	15 Jan 2021 21:57:18

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2021-01-10T18:26:35', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: '20db1b12-d458-47cd-b34b-65e9f307e209'	System	15 Jan 2021 21:57:18
User entered '10 Jan 2021 18:26:35'	System	15 Jan 2021 21:57:18

FDA-CBER-2022-1614-2473852

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:29:05

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2021-01-15T16:57:16', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd8a57943-e8a7-41e1-90ee-b5f6abcbacc6'	System	15 Jan 2021 21:57:34
User entered 'No (N)'	System	15 Jan 2021 21:57:34

US3492299

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:51

Have you been exposed to someone with 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) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2021-01-15T16:57:24', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd8a57943-e8a7-41e1-90ee-b5f6abcbacc6'	System	15 Jan 2021 21:57:34
User entered 'No (N)'	System	15 Jan 2021 21:57:34

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (26349E10-7E0B-4D73-8D72-5E09CBA71C84)', Time: '2021-01-15T16:57:27', User OID: 'PatientReportedOutcome (US3492299)', ODM File OID: 'd8a57943-e8a7-41e1-90ee-b5f6abcbacc6'	System	15 Jan 2021 21:57:34
User entered '15 Jan 2021 16:57:27'	System	15 Jan 2021 21:57:34

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 12:29:05

US3492299
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:29:05
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 12:29:05

US3492299
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:30:42
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:42:56

US3492299
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:30:42
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered '7 Jan 2021'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:42:56

US3492299
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:30:42
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:42:56

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US3492299
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:30:42
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'subject MIA'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:42:56

FDA-CBER-2022-1614-2473864

US3492299
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:30:42
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:36:14
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:43:42
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	30 Mar 2021 20:43:07

US3492299
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:30:42
User entered empty.	System	30 Mar 2021 20:43:42
User entered '1'	System	30 Mar 2021 20:43:07

FDA-CBER-2022-1614-2473866

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:45
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 20-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 20-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:00:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 20-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 20-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate. ' answered with 'it is recorded under illness visit 2 as per ePIP recommendation' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:36:16
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 20-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 20-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:43:45
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 22:40:20

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:45
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '11:00'	(b) (4), (b) (6)	12 Nov 2020 22:40:20

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '12 Nov 2020 11:00'	System	12 Nov 2020 22:40:20

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:45
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	12 Nov 2020 22:40:20

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:45
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 22:40:20

FDA-CBER-2022-1614-2473871

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473873

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473874

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473876

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473877

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473878

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473879

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473880

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473883

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473884

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473885

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473887

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473890

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

FDA-CBER-2022-1614-2473891

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:35

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473894

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473895

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473905

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473906

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473907

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473908

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473909

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473911

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

FDA-CBER-2022-1614-2473913

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:41:46

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473917

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '100'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '%'	System	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473920

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '96.8' F	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473921

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473922

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473923

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473924

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473926

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473927

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473928

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473929

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473931

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473933

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

FDA-CBER-2022-1614-2473935

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 22:43:21

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 4 (Day 4)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 21:20:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 21:20:28
User entered '13 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 21:18:34
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473939

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:59:56
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473941

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473942

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473943

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473944

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473946

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473947

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473949

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473951

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473952

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473953

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

FDA-CBER-2022-1614-2473954

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:18:34

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 5 (Day 5)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473960

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '14 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '99'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473963

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '%'	System	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473964

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '97.5' F	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473965

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473966

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473968

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473969

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473970

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473971

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473972

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473973

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473974

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473975

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

FDA-CBER-2022-1614-2473976

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	14 Nov 2020 21:20:28

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 6 (Day 6)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '15 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '100'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

FDA-CBER-2022-1614-2473985

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '%'	System	15 Nov 2020 22:16:53

FDA-CBER-2022-1614-2473986

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '97.5' F	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

FDA-CBER-2022-1614-2473993

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

FDA-CBER-2022-1614-2473994

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

FDA-CBER-2022-1614-2473995

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

FDA-CBER-2022-1614-2474001

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	15 Nov 2020 22:16:53

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '97'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '%'	System	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474008

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 20:41:12
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 20:41:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 20:41:02
User entered '97.8' (non-conformant).	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474010

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474011

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474012

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474014

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474016

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474017

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474019

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474020

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474022

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474023

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474024

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	(b) (4), (b) (6)	16 Nov 2020 20:41:02

FDA-CBER-2022-1614-2474025

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '17 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 19:14:33

FDA-CBER-2022-1614-2474027

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 19:14:33

FDA-CBER-2022-1614-2474028

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	23 Nov 2020 19:14:33

FDA-CBER-2022-1614-2474030

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

FDA-CBER-2022-1614-2474031

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

FDA-CBER-2022-1614-2474033

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

FDA-CBER-2022-1614-2474037

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

FDA-CBER-2022-1614-2474038

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

FDA-CBER-2022-1614-2474039

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:33

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '18 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 19:14:45

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	23 Nov 2020 19:14:45

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:14:45

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US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	23 Nov 2020 19:15:01

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '19 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474071

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474072

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474074

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474075

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474076

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474077

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474078

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474079

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474083

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474084

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474085

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474086

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474089

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:51
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 19:15:01

FDA-CBER-2022-1614-2474091

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474092

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474093

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474094

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474095

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474096

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474097

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474098

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474099

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474100

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474101

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474102

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474105

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474106

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474107

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474108

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474109

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474110

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474111

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474112

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 22:43:39

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 22:43:39

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:31:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:31:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 21:31:59
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 22:43:39
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:43:39

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 22:43:39

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	12 Nov 2020 22:43:39

FDA-CBER-2022-1614-2474118

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:43:39

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
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) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 22:43:39

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:43:39

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:43:39

FDA-CBER-2022-1614-2474122

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '0'	System	19 Nov 2020 21:31:59

US3492299
Folder: Covid-19 Assessment 12 Nov 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:46:51
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:35:59
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 22:26:36

FDA-CBER-2022-1614-2474124

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User closed query 'Per ETRTR, Please update Symptom log as appropriate following illness day 20Nov20. Thanks!' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:06:02
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:08
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Query 'Per ETRTR, Please update Symptom log as appropriate following illness day 20Nov20. Thanks!' answered with 'cannot, subject absconded and we cannot locate' (Site from CRA).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:50:08
User opened query 'Per ETRTR, Please update Symptom log as appropriate following illness day 20Nov20. Thanks!' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 14:46:16
User entered '20 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:47:31

FDA-CBER-2022-1614-2474125

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:08
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '09:30'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:47:31

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '20 Nov 2020 09:30'	System	27 Nov 2020 02:47:31

FDA-CBER-2022-1614-2474127

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:08
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Safety Call (Safety Call)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:47:31

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:51
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:08
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:47:31

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User closed query 'Please update symptom log as expected. Entries should be captured for a minimum of 14 days or until symptoms resolve, whichever is longer from the date of illness visit day 1.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Apr 2021 17:08:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Query 'Please update symptom log as expected. Entries should be captured for a minimum of 14 days or until symptoms resolve, whichever is longer from the date of illness visit day 1.' answered with 'completed as not done through D14 per ePIP recommendation as subject is MIA since 21Nov2020' (Site from CRA).	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:35:17
User opened query 'Please update symptom log as expected. Entries should be captured for a minimum of 14 days or until symptoms resolve, whichever is longer from the date of illness visit day 1.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 01:22:41
User entered 'Day 11 (Day 11)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474130

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '20 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474131

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474132

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '99'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474133

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '%'	System	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474134

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '99.7' F	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474135

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474136

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474137

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474139

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474140

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474141

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Moderate (Moderate)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474142

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474143

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474144

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474145

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474146

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474147

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474148

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474149

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'None (None)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

FDA-CBER-2022-1614-2474150

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:56:42

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 12 (Day 12)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '21 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474154

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474155

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474156

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474157

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474158

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474159

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474160

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474161

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474163

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474164

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474165

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474166

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474167

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474168

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474170

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474171

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474172

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474173

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 13 (Day 13)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474174

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '22 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474175

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474176

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474178

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474179

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474180

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474181

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474183

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474184

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474185

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474188

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474189

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474190

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474191

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474192

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474193

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474194

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 14 (Day 14)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '23 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474197

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474198

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474200

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474201

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474202

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474203

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474204

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474206

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474207

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474208

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474209

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474211

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474212

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474213

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474214

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474215

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474216

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:34:25

FDA-CBER-2022-1614-2474217

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 15 (Day 15)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '24 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474219

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474220

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474221

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474222

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474223

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474224

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474225

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474226

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474227

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474228

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474229

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474230

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474231

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474232

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474233

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474234

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474235

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474236

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474238

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474239

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 16 (Day 16)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474240

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '25 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474241

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474242

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474244

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474245

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474246

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474247

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474248

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474249

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474251

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474252

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474254

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474255

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474256

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474257

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474258

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474259

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474260

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474261

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 17 (Day 17)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '26 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474263

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474264

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474266

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474267

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474268

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474270

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474271

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474272

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474273

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474274

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474275

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474276

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474277

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474278

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474282

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 18 (Day 18)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474284

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '27 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474285

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474286

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474288

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474289

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474290

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474291

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474292

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474293

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474294

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474295

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474299

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474300

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 19 (Day 19)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '28 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474307

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474308

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474310

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474311

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474312

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474313

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474314

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474315

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474316

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474318

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474320

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474321

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474322

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474324

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474325

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474326

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 20 (Day 20)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '29 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474329

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474330

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474332

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474333

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474334

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474336

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474337

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474338

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474339

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474340

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474341

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474342

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474344

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474346

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474347

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474348

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:37:55

FDA-CBER-2022-1614-2474349

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 21 (Day 21)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474350

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '30 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474352

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474354

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474355

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474356

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474358

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474359

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474360

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474363

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474364

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474365

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474366

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474368

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474369

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474371

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 22 (Day 22)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1 Dec 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474374

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474376

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474377

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474378

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474379

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474380

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474382

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474383

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474384

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474385

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474386

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474387

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474388

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474389

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474391

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 23 (Day 23)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '2 Dec 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474395

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474396

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474398

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474399

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474401

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474402

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474404

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474406

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474407

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474408

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474409

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474410

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474412

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474414

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 24 (Day 24)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '3 Dec 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474417

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474418

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474419

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474420

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474421

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474422

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474423

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474424

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474426

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474427

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474428

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474429

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474430

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474431

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474432

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474433

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474434

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474435

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474436

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:39:25

FDA-CBER-2022-1614-2474437

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 25 (Day 25)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '4 Dec 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474439

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474442

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474443

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474444

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474446

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474447

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474448

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474449

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474452

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474456

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474457

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474458

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474459

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 26 (Day 26)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474460

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '5 Dec 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474461

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474462

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474464

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474465

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474466

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474467

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474468

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474469

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474471

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474472

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474473

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474474

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474475

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474476

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474477

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474478

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474479

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474480

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 27 (Day 27)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '6 Dec 2020'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474483

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474484

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474486

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474487

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474488

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474489

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474490

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474492

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474493

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474494

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474495

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474496

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474497

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474498

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474499

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Day 28 (Day 28)'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 21:51:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Dec 2020 21:51:09
User entered '7 Dec 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:09
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Dec 2020 15:40:40
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474505

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474506

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474508

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474509

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474510

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474511

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474512

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474513

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474514

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474515

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474516

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474517

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474518

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474519

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474520

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474522

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474523

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474524

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:51
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 15:40:40

FDA-CBER-2022-1614-2474525

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '20 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per CDM: It appears subject was confirmed Symptomatic Covid-19 yet AE event is named as Covid-19 Infection. Please consider updating to Covid-19 ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:08:59
Query 'Per CDM: It appears subject was confirmed Symptomatic Covid-19 yet AE event is named as Covid-19 Infection. Please consider updating to Covid-19 ' answered with 'corrected' (Site from DM).	Diana Bahena (b) (4) (b) (4)	25 Jan 2021 15:48:31
User opened query 'Per CDM: It appears subject was confirmed Symptomatic Covid-19 yet AE event is named as Covid-19 Infection. Please consider updating to Covid-19 ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 16:02:48
Query 'Per CDM: It appears subject was confirmed Symptomatic Covid-19 yet event is named as Covid-19 Infection. Please consider updating to Covid-19.' canceled (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 16:01:54
User opened query 'Per CDM: It appears subject was confirmed Symptomatic Covid-19 yet event is named as Covid-19 Infection. Please consider updating to Covid-19.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 16:01:44
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
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)	21 Dec 2020 11:50:34
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 'yes' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:21
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	27 Nov 2020 02:48:07
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

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Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Nov 2020 02:48:29
User entered '20 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Nov 2020 02:48:07
User entered '20 Nov ' (non-conformant).	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
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) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

FDA-CBER-2022-1614-2474533

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:48:07

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:51
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '1'	System	27 Nov 2020 02:48:07

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
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) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 17:49:19
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' answered with '----------reviewed and updated----------' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 20:12:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 20:11:28
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 16:03:38
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

FDA-CBER-2022-1614-2474572

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

FDA-CBER-2022-1614-2474574

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

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US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 20:11:28
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

US3492299
Folder: Covid-19 Assessment 20 Nov 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:51
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:57:18

FDA-CBER-2022-1614-2474586

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

FDA-CBER-2022-1614-2474592

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

FDA-CBER-2022-1614-2474595

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

FDA-CBER-2022-1614-2474596

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

FDA-CBER-2022-1614-2474598

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'NA (COVID-19 Negative) (NA)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:57
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:35:51

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query ' Per CDM: it appears there are 2 Covid Assessments (12NOV2020 and 20NOV2020) with Saliva Log not completed for 12NOV2020 yet recorded as NO for all days under 20NOV2020. Please clarify why no Saliva collected for 12NOV2020 Illness Visit or update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:45:35
Query ' Per CDM: it appears there are 2 Covid Assessments (12NOV2020 and 20NOV2020) with Saliva Log not completed for 12NOV2020 yet recorded as NO for all days under 20NOV2020. Please clarify why no Saliva collected for 12NOV2020 Illness Visit or update accordingly.' answered with 'They were not collected - ppt went out of the country' (Site from DM).	Diana Bahena (b) (4) (b) (4)	25 Jan 2021 15:50:40
User opened query ' Per CDM: it appears there are 2 Covid Assessments (12NOV2020 and 20NOV2020) with Saliva Log not completed for 12NOV2020 yet recorded as NO for all days under 20NOV2020. Please clarify why no Saliva collected for 12NOV2020 Illness Visit or update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:56:54
Query ' Per CDM: it appears there are 2 Covid Assessments (12NOV2020 and 19NOV2020) with Saliva Log not completed for 12NOV2020 yet recorded as NO for all days under 19NOV2020. Please clarify why no Saliva collected for 12NOV2020 Illness Visit or update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:56:13

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
User opened query ' Per CDM: it appears there are 2 Covid Assessments (12NOV2020 and 19NOV2020) with Saliva Log not completed for 12NOV2020 yet recorded as NO for all days under 19NOV2020. Please clarify why no Saliva collected for 12NOV2020 Illness Visit or update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:55:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

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US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

FDA-CBER-2022-1614-2474613

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

FDA-CBER-2022-1614-2474614

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Nov 2020 21:37:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Nov 2020 21:37:11
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:37:11
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:29:50
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

FDA-CBER-2022-1614-2474616

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

FDA-CBER-2022-1614-2474618

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Nov 2020 21:37:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Nov 2020 21:37:11
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:37:11
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:29:50
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

FDA-CBER-2022-1614-2474620

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

FDA-CBER-2022-1614-2474621

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Nov 2020 21:40:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Nov 2020 21:40:44
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:40:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:29:50
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

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US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Nov 2020 21:40:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Nov 2020 21:40:44
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:40:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:29:50
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

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US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:51
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:51
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Nov 2020 21:40:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Nov 2020 21:40:44
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:40:44
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 23:29:50
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

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US3492299
Folder: Illness Visit (2)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:38:02
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 23:29:50

FDA-CBER-2022-1614-2474629

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:37
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 18:26:53

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US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:37
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '12 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 18:26:53

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:37
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Nov 2020 18:26:53

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'SICKD1'	System	20 Nov 2020 18:26:53

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US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 18:28:05

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US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	20 Nov 2020 18:28:43
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	20 Nov 2020 18:28:43
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 18:28:43
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	20 Nov 2020 18:28:05
User entered '20 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 18:28:05

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US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '11:00'	(b) (4), (b) (6)	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474636

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '12 Nov 2020 11:00'	System	20 Nov 2020 18:28:43
User entered '20 Nov 2020 11:00'	System	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474637

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Nov 2020 18:28:43
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Nov 2020 18:28:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Nov 2020 18:28:05
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 18:28:05
DataPoint set to visible.	System	20 Nov 2020 18:26:53

FDA-CBER-2022-1614-2474638

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Nov 2020 18:28:43
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Nov 2020 18:28:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Nov 2020 18:28:05
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 18:28:05
DataPoint set to visible.	System	20 Nov 2020 18:26:53

FDA-CBER-2022-1614-2474639

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '96.8' F	(b) (4), (b) (6)	20 Nov 2020 18:28:05

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474641

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474642

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '85'	(b) (4), (b) (6)	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474643

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'bpm'	System	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474644

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '14'	(b) (4), (b) (6)	20 Nov 2020 18:28:05

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'breaths/min'	System	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474646

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '128'	(b) (4), (b) (6)	20 Nov 2020 18:28:05

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'mmHg'	System	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474648

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:41
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '85'	(b) (4), (b) (6)	20 Nov 2020 18:28:05

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'mmHg'	System	20 Nov 2020 18:28:05

FDA-CBER-2022-1614-2474650

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474651

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474652

US3492299
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:45
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 18:29:11

FDA-CBER-2022-1614-2474653

US3492299
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:45
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '12 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 18:29:11

FDA-CBER-2022-1614-2474654

US3492299
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:51
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:49
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 18:29:21

US3492299
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:36:49
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '12 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 18:29:21

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
User closed query 'Per ETRTR, Please Confirm if no Saliva was collected following illness visits. Thanks!' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:10:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:38
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Query 'Per ETRTR, Please Confirm if no Saliva was collected following illness visits. Thanks!' answered with 'this is correct. subject absconded and we are unable to locate' (Site from CRA).	Andrea Wendrow (b) (4)	16 Dec 2020 21:54:35
User opened query 'Per ETRTR, Please Confirm if no Saliva was collected following illness visits. Thanks!' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 14:19:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 22:27:16

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '20 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 22:27:16

FDA-CBER-2022-1614-2474658

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User closed query 'Per ETRTR, Please confirm if Illness Visit was performed at home or in the clinic. Thanks' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:11:07
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Query 'Per ETRTR, Please confirm if Illness Visit was performed at home or in the clinic. Thanks' answered with 'was at home' (Site from CRA).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:54:48
User opened query 'Per ETRTR, Please confirm if Illness Visit was performed at home or in the clinic. Thanks' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 14:12:46
User entered 'Home (Home)'	(b) (4), (b) (6)	20 Nov 2020 22:27:16

US3492299
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'SICKD1'	System	20 Nov 2020 22:27:16

FDA-CBER-2022-1614-2474660

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474661

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '20 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474662

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '15:57'	(b) (4), (b) (6)	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474663

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '20 Nov 2020 15:57'	System	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474664

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Nov 2020 22:29:12
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Nov 2020 22:29:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 22:29:12
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Nov 2020 22:28:53
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 22:28:53
DataPoint set to visible.	System	20 Nov 2020 22:27:16

FDA-CBER-2022-1614-2474665

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Nov 2020 22:29:12
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Nov 2020 22:29:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 22:29:12
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Nov 2020 22:28:53
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 22:28:53
DataPoint set to visible.	System	20 Nov 2020 22:27:16

FDA-CBER-2022-1614-2474666

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 22:29:36
User entered '99.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 22:29:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 22:28:53
User entered '99.8' (non-conformant).	(b) (4), (b) (6)	20 Nov 2020 22:28:53

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Nov 2020 22:28:53

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474669

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '95'	(b) (4), (b) (6)	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474670

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'bpm'	System	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474671

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '16'	(b) (4), (b) (6)	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474672

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'breaths/min'	System	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474673

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '132'	(b) (4), (b) (6)	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474674

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'mmHg'	System	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474675

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:43
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '78'	(b) (4), (b) (6)	20 Nov 2020 22:28:53

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'mmHg'	System	20 Nov 2020 22:28:53

FDA-CBER-2022-1614-2474677

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474678

US3492299
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474679

US3492299
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:46
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 22:29:47

US3492299
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:46
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '20 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 22:29:47

US3492299
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:51
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:50
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 22:29:58

US3492299
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:37:50
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 20 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 09:40:15
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 20 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'it is in there ,we have report accession number is 1F650503910. Preclarus still has as shipped from site' (Site from DM).	Andrea Wendrow (b) (4)	16 Dec 2020 21:53:52
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 20 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:32:03
User entered '20 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 22:29:58

FDA-CBER-2022-1614-2474683

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:36

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:36

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:36

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'SICKD28'	System	16 Dec 2020 21:51:36

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	16 Dec 2020 21:51:47

FDA-CBER-2022-1614-2474696

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	16 Dec 2020 21:51:47

FDA-CBER-2022-1614-2474698

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	16 Dec 2020 21:51:47

FDA-CBER-2022-1614-2474700

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:27
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	16 Dec 2020 21:51:47

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474703

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:51
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474704

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:31
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:53

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:31
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:53

FDA-CBER-2022-1614-2474706

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:51
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:34
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:59

US3492299
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:51
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:22:34
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:51:59

US3492299
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:57:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 18:14:12

US3492299
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:57:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 18:14:12

US3492299
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:57:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 18:14:12

US3492299
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered 'UNBLND_DECIDE'	System	07 Mar 2021 18:14:12

FDA-CBER-2022-1614-2474712

US3492299
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:46:51
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:06
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	26 Nov 2020 20:23:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:41:53

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:35:56
User entered 'USA-US101-2020-mRNA-1273-P301000008'	System	02 Dec 2020 18:35:48
User entered 'New'	(b) (4), (b) (6)	02 Dec 2020 18:35:48

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:49:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:49:55
Data point term sent to Coder	System	25 Jan 2021 15:48:46
Coding entries removed.	Diana Bahena (b) (4) (b) (4)	25 Jan 2021 15:48:14
User entered 'COVID-19' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	25 Jan 2021 15:48:14
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Nov 2020 02:52:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Nov 2020 02:52:07
Data point term sent to Coder	System	27 Nov 2020 02:51:10
User entered 'COVID-19 infection'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'PV Query: Day 1 of symptom log was 10 Nov 2020. Per EDC, the event start date was 20 Nov 2020. Please confirm the event start date (the day subject began to experience symptoms).' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:39:09
Query 'PV Query: Day 1 of symptom log was 10 Nov 2020. Per EDC, the event start date was 20 Nov 2020. Please confirm the event start date (the day subject began to experience symptoms).' answered with 'corrected' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:57:26
User entered '10 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:57:17
User opened query 'PV Query: Day 1 of symptom log was 10 Nov 2020. Per EDC, the event start date was 20 Nov 2020. Please confirm the event start date (the day subject began to experience symptoms).' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:49:36
User entered '20 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. If subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 00:11:53
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. If subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' answered with 'subject is lost to follow up. No response to emails, phone messages to ER contact either' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:37:45
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. If subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 19:44:28

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US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:39:12
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'end date unknow currently, subject absconded on 21Nov2020 and we cannot locate' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:58:08
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:49:09
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

FDA-CBER-2022-1614-2474724

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	27 Nov 2020 02:50:37

FDA-CBER-2022-1614-2474726

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

FDA-CBER-2022-1614-2474727

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

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US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 05:56:42
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'It is an AE-COVID-19 infection. And happened before D29 second dose so was withdrawn, no other action choice' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 16:30:08
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	01 Dec 2020 16:12:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#4) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 12:56:42
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#4) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	02 Feb 2021 16:20:45
User entered '0' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	02 Feb 2021 16:20:37
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#4) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:16:12
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '1' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	02 Feb 2021 16:20:37
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. If subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 00:12:01
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. If subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' answered with 'subject is lost to follow up. No response to emails, phone messages to ER contact either' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:37:51
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. If subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 19:44:00
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:39:16

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Outcome

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'end date unknow currently, subject absconded on 21Nov2020 and we cannot locate' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:58:18
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:48:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:11
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'PV Query: Please complete the symptom log for the duration of COVID symptoms experienced, if subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 00:12:05
Query 'PV Query: Please complete the symptom log for the duration of COVID symptoms experienced, if subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' answered with 'subject is lost to follow up. No response to emails, phone messages to ER contact either' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:37:58
User opened query 'PV Query: Please complete the symptom log for the duration of COVID symptoms experienced, if subject is lost to follow-up and no further updates are expected, else please consider leaving query open until additional follow-up has been received.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 19:43:37
User closed query 'PV Query: Please complete the symptom log for the duration of COVID symptoms experienced.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:39:21
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. If unknown please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 16:39:18
Query 'PV Query: Please complete the symptom log for the duration of COVID symptoms experienced.' answered with 'end date unknow currently, subject absconded on 21Nov2020 and we cannot locate' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:58:44
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. If unknown please state so.' answered with 'family member exposure' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:58:40

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please complete the symptom log for the duration of COVID symptoms experienced.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:48:26
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. If unknown please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:48:09
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '0'	System	27 Nov 2020 02:50:37

US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '1'	System	27 Nov 2020 02:50:37

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US3492299
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:51
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29

FDA-CBER-2022-1614-2474752

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 11 Aug 2021 22:46:51
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:37:19

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:40:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:40:19
Data point term sent to Coder	System	15 Oct 2020 00:39:24
User entered 'testosterone cypionate'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

FDA-CBER-2022-1614-2474755

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'hypogonadism'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

FDA-CBER-2022-1614-2474756

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:51:51
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 16:37:27
User entered '100' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 16:37:17
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:00:36
User entered '0.5'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'mg (mg)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 16:37:17
User entered 'mL (mL)'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'every week (QS)'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'un UNK 2012'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

FDA-CBER-2022-1614-2474764

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:38:47

FDA-CBER-2022-1614-2474768

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '1'	System	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '1'	System	15 Oct 2020 00:38:47

FDA-CBER-2022-1614-2474770

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '803 (803)'	System	15 Oct 2020 00:38:47

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: GONADOTROPINS AND OTHER OVULATION STIMULANTS, ATC: GONADOTROPINS, PRODUCT: CHORIONIC GONADOTROPHIN, PRODUCTSYNONYM: HCG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:42:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:42:21
Data point term sent to Coder	System	15 Oct 2020 00:41:25
User entered 'hcg'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

FDA-CBER-2022-1614-2474772

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

FDA-CBER-2022-1614-2474773

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'hypogonadism'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, 1000 units, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:51:57
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, 1000 units, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 16:44:25
User entered '150' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 16:43:58
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, 1000 units, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 07:00:54
User entered '0.3'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'ug (ug)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	06 Dec 2020 16:43:58
User entered 'mL (mL)'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'other (OTHER)'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'twice a week'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

FDA-CBER-2022-1614-2474779

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'un UNK 2010'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

FDA-CBER-2022-1614-2474782

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:40:55

FDA-CBER-2022-1614-2474786

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	15 Oct 2020 00:40:55

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:43:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:43:22
Data point term sent to Coder	System	15 Oct 2020 00:42:26
User entered 'loratidine'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

FDA-CBER-2022-1614-2474790

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'seasonal allergies'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

FDA-CBER-2022-1614-2474792

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '10'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'as needed (PRN)'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'un UNK 2010'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:41:40

FDA-CBER-2022-1614-2474804

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	15 Oct 2020 00:41:40

FDA-CBER-2022-1614-2474806

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered empty.	System	15 Oct 2020 00:41:40

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 22:01:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 22:01:34
Data point term sent to Coder	System	16 Dec 2020 22:00:07
Coding entries removed.	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:59:50
User entered 'ACETaMINOPHEN' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:59:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:01:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:01:48
Data point term sent to Coder	System	20 Nov 2020 22:32:03
User entered 'Acetominophen'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 01:50:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'yes there is' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	16 Dec 2020 21:59:15
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:48:46
User entered 'Fevers - COVID 19'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

FDA-CBER-2022-1614-2474810

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '500'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'four times daily (QID)'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '20 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '0'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '4'	System	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '1'	System	20 Nov 2020 22:31:37

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US3492299
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User entered '804 (804)'	System	20 Nov 2020 22:31:37

US3492299
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 11 Aug 2021 22:46:51
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:41:48

FDA-CBER-2022-1614-2474826

US3492299
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:46:51
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '25 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	01 Dec 2020 16:12:35

FDA-CBER-2022-1614-2474827

US3492299
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:46:51
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Due to SARS-COV-2 (COVID)'	Andrea Wendrow (b) (4) (b) (4)	01 Dec 2020 16:12:35

US3492299
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:46:51
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	01 Dec 2020 16:12:35

US3492299
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:51
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '20 Jan 2021'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:40:30

US3492299
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:51
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:40:30

FDA-CBER-2022-1614-2474831

US3492299
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:51
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:40:30

US3492299
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:51
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:40:30

US3492299
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:51
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:40:30

FDA-CBER-2022-1614-2474834

US3492299
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:51
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:40:30

FDA-CBER-2022-1614-2474835

US3492299
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:51
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:26:18
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	20 Jan 2021 23:40:30

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'USA-US101-2020-MRNA-1273-P301000008'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474837

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474840

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474842

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Richard'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Novak'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474846

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered '808 S. Wood St'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Chicago'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474848

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'IL'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered '60612'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 16:10:29
User entered 'US'	System	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '3'	System	22 Jan 2021 00:12:23
User entered '2'	System	17 Dec 2020 16:10:39
User entered '1'	System	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'USA-US101-2020-MRNA-1273-P301000008'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474856

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Richard'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474861

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Novak'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474862

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered '808 S. Wood St'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Chicago'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'IL'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered '60612'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 16:10:29
User entered 'US'	System	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '3'	System	22 Jan 2021 00:12:23
User entered '2'	System	17 Dec 2020 16:10:39
User entered '1'	System	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form (1)
Generated On: 11 Aug 2021 22:46:51
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '02/Dec/2020 18:36'	System	02 Dec 2020 18:36:14

US3492299

Folder: SAE USA-US101-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:46:51

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) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 16:10:29
User entered '1'	(b) (4), (b) (6)	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'USA-US101-2020-MRNA-1273-P301000008'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474871

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Richard'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Novak'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered '808 S. Wood St'	System (b) (4), (b) (6)	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Chicago'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'IL'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered '60612'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 16:10:29
User entered 'US'	System	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '3'	System	22 Jan 2021 00:12:23
User entered '2'	System	17 Dec 2020 16:10:39
User entered '1'	System	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form (2)
Generated On: 11 Aug 2021 22:46:51
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '17/Dec/2020 11:10'	System	17 Dec 2020 16:10:39

US3492299

Folder: SAE USA-US101-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:46:51

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)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 00:12:13
User entered '1'	(b) (4), (b) (6)	17 Dec 2020 16:10:39

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'USA-US101-2020-MRNA-1273-P301000008'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'No (N)'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Richard'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Novak'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered '808 S. Wood St'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'Chicago'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered 'IL'	System	02 Dec 2020 18:35:48

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 18:36:09
User entered '60612'	System	02 Dec 2020 18:35:48

FDA-CBER-2022-1614-2474902

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 16:10:29
User entered 'US'	System	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:51
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '3'	System	22 Jan 2021 00:12:23
User entered '2'	System	17 Dec 2020 16:10:39
User entered '1'	System	02 Dec 2020 18:36:14

US3492299
Folder: SAE USA-US101-2020-MRNA-1273-P301000008
Form: Safety Report Form (3)
Generated On: 11 Aug 2021 22:46:51
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 04:37:25
User entered '22/Jan/2021 00:12'	System	22 Jan 2021 00:12:23

US3492299

Folder: SAE USA-US101-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:46:51

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)	02 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:02:01
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 04:37:25
User entered '1'	(b) (4), (b) (6)	22 Jan 2021 00:12:23