US3452232 (Prod: Lynn Health Science Institute)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:46:20

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US3452232
Form: Participant Creation
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Participant ID	US3452232

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0995610

US3452232
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995611

US3452232
Folder: Screening
Form: Demographics
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Date of Birth (MMM yyyy)	(b) (6) 1983
Age	37
Age Units	YEARS
Age (Derived)	37
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-2022-1614-0995612

US3452232
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Date of Informed Consent *(dd MMM yyyy)*	05 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ■ Amendment 2 ☐ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-0995613

US3452232
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Did the participant meet all eligibility criteria?

Yes ■
No ☐

FDA-CBER-2022-1614-0995614

US3452232
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0995615

US3452232
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Condition	FARSIGHTED
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0995616

US3452232
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0995617

US3452232
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0995618

US3452232
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0995619

US3452232
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0995620

US3452232
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0995621

US3452232
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Condition	ALLERGY TO KEFLEX
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0995622

US3452232
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	05 AUG 2020
Time of assessment *(00:00-23:59)*	10:09 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 10:09
Height *(xxx.x)*	68 in
Weight *(xxx.x)*	181.4 lb
BMI *(xxx.x)*	27.63945 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0995623

US3452232
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	05 AUG 2020

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

FDA-CBER-2022-1614-0995624

US3452232
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **17 Feb 2021 18:08:05**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ■ No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	

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

US3452232
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **17 Feb 2021 18:08:05**
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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3452232
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0995627

US3452232
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

What was the date of randomization? *(dd MMM yyyy)*	05 AUG 2020
What was the participant's randomization number?	101225
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ■ >=18 and <65 years and at risk ☐ >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ☐ No ■
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ☐ No ■
Severe obesity (body mass index > or = 40kg/m2	Yes ☐ No ■
Diabetes (Type I, Type 2, or gestational)	Yes ☐ No ■
Liver Disease	Yes ☐ No ■

FDA-CBER-2022-1614-0995628

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0995629

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

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)*	05 AUG 2020
Time of assessment *(00:00-23:59)*	10:09 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 10:09
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	74 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	94 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0995630

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

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)*	05 AUG 2020
Time of assessment *(00:00-23:59)*	11:16 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 11:16
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ● Axillary ○ Other ○
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0995631

US3452232
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	05 AUG 2020

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

FDA-CBER-2022-1614-0995632

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

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)*	05 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:29 (24 HR)
Treatment Date and Time (derived)	05 AUG 2020 10:29
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-2022-1614-0995633

US3452232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	05 AUG 2020
Collection time *(00:00-23:59)*	10:13 (24 HR)
Collection date and time (derived)	05 AUG 2020 10:13

FDA-CBER-2022-1614-0995634

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Collection date *(dd MMM yyyy)*			05 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:11	05 AUG 2020 10:11
Nasopharyngeal Swab 2	Yes	10:11	05 AUG 2020 10:11

FDA-CBER-2022-1614-0995635

US3452232
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995636

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 AUG 2020 11:13
PC Open Date & Time	05 AUG 2020 10:49
PC Close Date & Time	05 AUG 2020 13:19

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 AUG 2020 14:20
PC Open Date & Time	05 AUG 2020 14:14
PC Close Date & Time	06 AUG 2020 11:59

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 AUG 2020 12:43
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 AUG 2020 22:58
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 AUG 2020 13:25
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

TIMEPOINT	DAY 5

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

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

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**	96.7 °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	09 AUG 2020 19:11
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.7 °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	10 AUG 2020 23:59
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0995643

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 AUG 2020 15:37
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	05 AUG 2020 11:14
PC Open Date & Time	05 AUG 2020 10:49
PC Close Date & Time	05 AUG 2020 13:19

FDA-CBER-2022-1614-0995645

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	05 AUG 2020 14:20
PC Open Date & Time	05 AUG 2020 14:14
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-0995646

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	06 AUG 2020 12:04
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	07 AUG 2020 18:07
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

FDA-CBER-2022-1614-0995648

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	08 AUG 2020 13:25
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0995649

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	09 AUG 2020 19:10
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

FDA-CBER-2022-1614-0995650

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995651

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	11 AUG 2020 15:36
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0995652

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 ☐

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 AUG 2020 11:14
PC Open Date & Time	05 AUG 2020 10:49
PC Close Date & Time	05 AUG 2020 13:19

FDA-CBER-2022-1614-0995654

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 ☐

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	05 AUG 2020 14:20
PC Open Date & Time	05 AUG 2020 14:14
PC Close Date & Time	06 AUG 2020 11:59

FDA-CBER-2022-1614-0995656

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 ■

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20

	Yes ☐
PC Time stamp	06 AUG 2020 12:04
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

FDA-CBER-2022-1614-0995658

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 ■

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20

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

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

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20

	Yes ☐
PC Time stamp	08 AUG 2020 13:26
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

FDA-CBER-2022-1614-0995662

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 ■

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20

	Yes
PC Time stamp	09 AUG 2020 19:10
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

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 ■

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995666

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 ■

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20

	Yes ☐
PC Time stamp	11 AUG 2020 15:36
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0995668

US3452232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0995669

US3452232
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **17 Feb 2021 18:08:05**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995670

US3452232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0995671

US3452232
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995672

US3452232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **17 Feb 2021 18:08:02**
Generated On: 11 Aug 2021 22:46:20

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

US3452232
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **17 Feb 2021 18:08:02**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995674

US3452232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0995675

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 SEP 2020
Time of assessment *(00:00-23:59)*	09:16 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:16
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	67 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0995676

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 SEP 2020
Time of assessment *(00:00-23:59)*	10:05 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:05
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0995677

US3452232
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	08 SEP 2020

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

FDA-CBER-2022-1614-0995678

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

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)*	08 SEP 2020
What was the treatment time? *(00:00-23:59)*	09:29 (24 HR)
Treatment Date and Time (derived)	08 SEP 2020 09:29
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-2022-1614-0995679

US3452232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	08 SEP 2020
Collection time *(00:00-23:59)*	09:18 (24 HR)
Collection date and time (derived)	08 SEP 2020 09:18

FDA-CBER-2022-1614-0995680

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Collection date *(dd MMM yyyy)*			08 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:20	08 SEP 2020 09:20
Nasopharyngeal Swab 2	Yes	09:20	08 SEP 2020 09:20

FDA-CBER-2022-1614-0995681

US3452232
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995682

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**	98.5 °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	08 SEP 2020 10:04
PC Open Date & Time	08 SEP 2020 09:49
PC Close Date & Time	08 SEP 2020 12:19

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 19:08
PC Open Date & Time	08 SEP 2020 13:14
PC Close Date & Time	09 SEP 2020 11:59

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 SEP 2020 17:20
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	10 SEP 2020 12:20
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 SEP 2020 07:52
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

TIMEPOINT	DAY 5

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

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

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**	96.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 SEP 2020 08:59
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

TIMEPOINT	DAY 6

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 SEP 2020 12:01
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20

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.

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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**	96.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	15 SEP 2020 05:59
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20

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	08 SEP 2020 10:05
PC Open Date & Time	08 SEP 2020 09:49
PC Close Date & Time	08 SEP 2020 12:19

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US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20

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	08 SEP 2020 19:07
PC Open Date & Time	08 SEP 2020 13:14
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-0995692

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20

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	09 SEP 2020 17:18
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-0995693

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20

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	10 SEP 2020 12:18
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0995694

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20

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	12 SEP 2020 07:51
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-0995695

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20

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	13 SEP 2020 08:57
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-0995696

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995697

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20

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	15 SEP 2020 05:59
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0995698

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 ☐

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	08 SEP 2020 10:05
PC Open Date & Time	08 SEP 2020 09:49
PC Close Date & Time	08 SEP 2020 12:19

FDA-CBER-2022-1614-0995700

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 ☐

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	08 SEP 2020 19:08
PC Open Date & Time	08 SEP 2020 13:14
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-0995702

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 ■

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20

	Yes
PC Time stamp	09 SEP 2020 17:19
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

TIMEPOINT	DAY 3
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20

	Yes
PC Time stamp	10 SEP 2020 12:18
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

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

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20

	Yes ☐
PC Time stamp	12 SEP 2020 07:51
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-0995708

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 ■

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20

	Yes ☐
PC Time stamp	13 SEP 2020 08:57
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-0995710

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 ■

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20

	Yes
PC Time stamp	13 SEP 2020 12:01
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

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

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20

	Yes ☐
PC Time stamp	15 SEP 2020 05:59
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0995714

US3452232
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **HEADACHE**	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	15 SEP 2020 15:21
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-0995715

US3452232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	15 SEP 2020 15:21
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-0995716

US3452232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **17 Feb 2021 18:08:02**
Generated On: 11 Aug 2021 22:46:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0995717

US3452232
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **17 Feb 2021 18:08:02**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995718

US3452232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **17 Feb 2021 18:08:02**
Generated On: 11 Aug 2021 22:46:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0995719

US3452232
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **17 Feb 2021 18:08:02**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995720

US3452232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **17 Feb 2021 18:08:02**
Generated On: 11 Aug 2021 22:46:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0995721

US3452232
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **17 Feb 2021 18:08:02**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995722

US3452232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0995723

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

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-2022-1614-0995724

US3452232
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	07 OCT 2020

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

FDA-CBER-2022-1614-0995725

US3452232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	07 OCT 2020
Collection time *(00:00-23:59)*	09:25 (24 HR)
Collection date and time (derived)	07 OCT 2020 09:25

FDA-CBER-2022-1614-0995726

US3452232
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **17 Feb 2021 18:08:06**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995727

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 OCT 2020 08:12:39
Patient Cloud Open Date & Time	05 OCT 2020 00:01
Patient Cloud Close Date & Time	09 OCT 2020 23:59

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 07:58:52
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

FDA-CBER-2022-1614-0995729

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 OCT 2020 08:26:55
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

FDA-CBER-2022-1614-0995730

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 12:34:33
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

FDA-CBER-2022-1614-0995731

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 08:30:50
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 07:48:03
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

FDA-CBER-2022-1614-0995733

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 08:23:53
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

FDA-CBER-2022-1614-0995734

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 07:50:58
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

FDA-CBER-2022-1614-0995735

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 12:01:03
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	11 DEC 2020 18:26:32
Patient Cloud Open Date & Time	11 DEC 2020 00:01

Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 05:06:23
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 02:52:54
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 12:01:13
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 10:10:08
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

FDA-CBER-2022-1614-0995742

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 07:24:35
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 09:26:56
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 13:32:48
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

FDA-CBER-2022-1614-0995745

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 09:02:16
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 07:41:14
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 07:34:17
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3452232
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995749

US3452232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995750

US3452232
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995751

US3452232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0995752

US3452232
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995753

US3452232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	06 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0995754

US3452232
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995755

US3452232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0995756

US3452232
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995757

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID-19 Contact
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Date of Contact	11 DEC 2020
Time of Contact	07:50
Date and Time of Contact (derived)	11 DEC 2020 07:50
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-2022-1614-0995758

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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-2022-1614-0995759

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	11 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

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

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

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	12 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

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

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

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	13 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	14 DEC 2020
Assessment Not Done	False
O2 Saturation	ND - Not Done
O2 Saturation Units	%
Temperature	ND - Not Done
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	15 DEC 2020
Assessment Not Done	False
O2 Saturation	100 %
O2 Saturation Units	%
Temperature	98.4 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	16 DEC 2020
Assessment Not Done	False
O2 Saturation	96 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	17 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.9 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

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	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	18 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.5 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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	19 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	98.0 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

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

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

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	20 DEC 2020
Assessment Not Done	False
O2 Saturation	97 %
O2 Saturation Units	%
Temperature	99.8 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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	21 DEC 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	99.9 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ○

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	22 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	100.5 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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	23 DEC 2020
Assessment Not Done	False
O2 Saturation	88 %
O2 Saturation Units	%
Temperature	101.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	24 DEC 2020
Assessment Not Done	False
O2 Saturation	88 %
O2 Saturation Units	%
Temperature	101.7 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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	25 DEC 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	101.0 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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-2022-1614-0995819

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	26 DEC 2020
Assessment Not Done	False
O2 Saturation	86 %
O2 Saturation Units	%
Temperature	98.9 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	27 DEC 2020
Assessment Not Done	False
O2 Saturation	88 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	28 DEC 2020
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	98.9 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ■
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

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

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Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	29 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.9 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

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

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

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Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	30 DEC 2020
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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

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

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Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	31 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

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Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	01 JAN 2021
Assessment Not Done	False
O2 Saturation	90 %
O2 Saturation Units	%
Temperature	98.7 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	02 JAN 2021
Assessment Not Done	False
O2 Saturation	90 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	03 JAN 2021
Assessment Not Done	False
O2 Saturation	93 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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-2022-1614-0995855

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	04 JAN 2021
Assessment Not Done	False
O2 Saturation	90 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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-2022-1614-0995859

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	05 JAN 2021
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	98.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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-2022-1614-0995863

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	06 JAN 2021
Assessment Not Done	False
O2 Saturation	92 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

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

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

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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-2022-1614-0995867

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	07 JAN 2021
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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-2022-1614-0995871

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	08 JAN 2021
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

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

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

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	09 JAN 2021
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	10 JAN 2021
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	98.2 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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	11 JAN 2021
Assessment Not Done	False
O2 Saturation	95 %
O2 Saturation Units	%
Temperature	98.6 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ■
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

	Day 33 ■ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	12 JAN 2021
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	98.1 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ☐ Mild ■ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

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

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 ☐

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Date of Visit	15 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ■ No ☐
Date of Test	15 DEC 2020
Type of Test Performed	Nasopharyngeal Swab ■ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ■
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

Did the subject have Respiratory Rates ≥ 30 per Minute?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Respiratory Rate	
Did the subject have Heart Rate ≥ 125 beats per minute	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
Heart Rate	
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?	Yes ■ No ☐
If Yes, provide:	
Start Date	23 DEC 2020
End Date	06 JAN 2021
Oxygen Saturation	86 %
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?	Yes ☐ No ■
If Yes, provide:	
Start Date	
End Date	
PaO2	
Did the subject have Respiratory failure?	Yes ☐ No ■
Start Date	
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?	Yes ☐ No ■
Start Date	

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

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

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

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

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-0995895

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 DEC 2020
Day 5	Yes	20 DEC 2020
Day 7	Yes	22 DEC 2020
Day 9	Yes	24 DEC 2020
Day 14	Yes	29 DEC 2020
Day 21	Yes	05 JAN 2021
Day 28	Yes	12 JAN 2021

FDA-CBER-2022-1614-0995896

US3452232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	15 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-0995897

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	15 DEC 2020
Time of assessment *(00:00-23:59)*	11:08 (24 HR)
Vital Signs Date and Time (derived)	15 DEC 2020 11:08
Height *(xxx.x)*	68.0 in
Weight *(xxx.x)*	178.4 lb
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	82 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0995898

US3452232
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	15 DEC 2020

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

FDA-CBER-2022-1614-0995899

US3452232
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	15 DEC 2020

FDA-CBER-2022-1614-0995900

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	12 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD28

FDA-CBER-2022-1614-0995901

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	12 JAN 2021
Time of assessment *(00:00-23:59)*	12:54 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 12:54
Height *(xxx.x)*	68.0 in
Weight *(xxx.x)*	191.8 lb
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	100 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0995902

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	12 JAN 2021

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

FDA-CBER-2022-1614-0995903

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	12 JAN 2021

FDA-CBER-2022-1614-0995904

US3452232
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **13 Mar 2021 17:17:18**
Generated On: 11 Aug 2021 22:46:20

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0995905

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **13 Mar 2021 17:17:18**
Generated On: 11 Aug 2021 22:46:20

AEID	USA-US208-2020-MRNA-1273-P30 1000013
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)*	11 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	12 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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

Narrative

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **13 Mar 2021 17:17:18**
Generated On: 11 Aug 2021 22:46:20

	SUBJECT WAS CONTACTED ABOUT DIARY ENTRY. HE STATED THAT HIS WIFE TESTED POSITIVE FOR COVID 11DEC2020. HE STATED THAT HE STARTED HAVING SOME NASAL CONGESTION BUT THAT WAS IT. HE WAS CURRENTLY OUT OF TOWN WHEN WE SPOKE AND STATED HE WOULD BE BACK ON 14DEC2020 LATE. HE WAS ASKED TO COME IN ON TUESDAY 15DEC2020 WHICH HE DID.
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)	

FDA-CBER-2022-1614-0995908

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **16 Apr 2021 03:13:09**
Generated On: 11 Aug 2021 22:46:20

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

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

FDA-CBER-2022-1614-0995909

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **16 Apr 2021 03:13:09**
Generated On: 11 Aug 2021 22:46:20

Name of Medication	FAMOTIDINE
Prophylaxis	Yes ☐ No ■
Indication	INTERMITTENT HEARTBURN
Dose per administration	20
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **16 Apr 2021 03:13:09**
Generated On: 11 Aug 2021 22:46:20

Name of Medication	MONTELUKAST
Prophylaxis	Yes ☐ No ■
Indication	INTERMITTENT 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 ☐
	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 2018
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 ■

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **16 Apr 2021 03:13:09**
Generated On: 11 Aug 2021 22:46:20

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes ☐ No ■
Indication	COVID-19
Dose per administration	6
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	23 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	28 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **16 Apr 2021 03:13:09**
Generated On: 11 Aug 2021 22:46:20

Name of Medication	IVERMECTIN
Prophylaxis	Yes ☐ No ■
Indication	COVID-19
Dose per administration	200
Dose unit	mg ☐ ug ■ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	23 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	23 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3452232
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **16 Apr 2021 03:43:39**
Generated On: 11 Aug 2021 22:46:20

Were any concomitant procedures performed?	Yes ☐ No ☒

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0995918

US3452232
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 11 Aug 2021 22:46:20

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

FDA-CBER-2022-1614-0995919

US3452232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

Date of study discontinuation/completion *(dd MMM yyyy)*	22 FEB 2021
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ■ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT STATED THAT HIS WORK SCHEDULE HAS INCREASED SO MUCH THAT HE IS UNABLE TO COME.
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-0995920

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

SAEID	USA-US208-2020-MRNA-1273-P301000013
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	CARL
Investigator's Last Name	GRIFFIN
Site Address: Street	3555 NW 58TH STRET
Site Address: City	OKC
Site Address: State	
Site Address: Postal Code	73112
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (1)
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

SAEID	USA-US208-2020-MRNA-1273-P301000013
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	CARL
Investigator's Last Name	GRIFFIN
Site Address: Street	3555 NW 58TH STRET
Site Address: City	OKC
Site Address: State	
Site Address: Postal Code	73112
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/DEC/2020 10:41
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

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (2)
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

SAEID	USA-US208-2020-MRNA-1273-P301000013
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	CARL
Investigator's Last Name	GRIFFIN
Site Address: Street	3555 NW 58TH STRET
Site Address: City	OKC
Site Address: State	
Site Address: Postal Code	73112
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/DEC/2020 20:13
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

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (3)
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

SAEID	USA-US208-2020-MRNA-1273-P301000013
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	CARL
Investigator's Last Name	GRIFFIN
Site Address: Street	3555 NW 58TH STRET
Site Address: City	OKC
Site Address: State	
Site Address: Postal Code	73112
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/FEB/2021 15:32
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

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (4)
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

SAEID	USA-US208-2020-MRNA-1273-P301000013
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	CARL
Investigator's Last Name	GRIFFIN
Site Address: Street	3555 NW 58TH STRET
Site Address: City	OKC
Site Address: State	
Site Address: Postal Code	73112
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/FEB/2021 09:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (5)
Data signed: (b) (4) **16 Apr 2021 03:43:41**
Generated On: 11 Aug 2021 22:46:20

SAEID	USA-US208-2020-MRNA-1273-P301000013
Serious	Yes ☐ No ■
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	CARL
Investigator's Last Name	GRIFFIN
Site Address: Street	3555 NW 58TH STRET
Site Address: City	OKC
Site Address: State	
Site Address: Postal Code	73112
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	31/MAR/2021 13:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3452232 (Prod: Lynn Health Science Institute)

US3452232
Form: Participant Creation
Generated On: 11 Aug 2021 22:46:20
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'US3452232'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:24:47

FDA-CBER-2022-1614-0995928

US3452232
Form: Participant Creation
Generated On: 11 Aug 2021 22:46:20

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0995929

US3452232
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:05

FDA-CBER-2022-1614-0995930

US3452232
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:24:48

FDA-CBER-2022-1614-0995931

US3452232
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:05

FDA-CBER-2022-1614-0995932

US3452232
Folder: Screening
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'SCRN'	System	05 Aug 2020 14:31:05

FDA-CBER-2022-1614-0995933

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered (b) (6) 1983'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:24:49

FDA-CBER-2022-1614-0995934

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '37'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995935

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'YEARS'	System	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995936

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '37'	System	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995937

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Male (M)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995938

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995939

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '1'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995940

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995941

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995942

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995943

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995944

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995945

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995946

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995947

US3452232
Folder: Screening
Form: Demographics
Generated On: 11 Aug 2021 22:46:20
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:20

FDA-CBER-2022-1614-0995948

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995949

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'Aug 2020'	System	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995950

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '2020'	System	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995951

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Amendment 1 (1)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995952

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995953

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995954

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995955

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:23

FDA-CBER-2022-1614-0995956

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:24:48

FDA-CBER-2022-1614-0995957

US3452232
Folder: Screening
Form: Enrollment
Generated On: 11 Aug 2021 22:46:20
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	05 Aug 2020 14:31:27

FDA-CBER-2022-1614-0995958

US3452232
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 11 Aug 2021 22:46:20
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:27

FDA-CBER-2022-1614-0995959

US3452232
Folder: Screening
Form: Medical History Summary
Generated On: 11 Aug 2021 22:46:20
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:09:40

FDA-CBER-2022-1614-0995960

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:12:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:12:10
Data point term sent to Coder	System	05 Aug 2020 18:11:04
User entered 'FARSIGHTED'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995961

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'UN UNK 2018'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995962

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995963

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:19

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995965

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995966

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'Jan 2018'	System	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995967

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '2018'	System	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995968

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995969

US3452232
Folder: Screening
Form: Medical History (1)
Generated On: 11 Aug 2021 22:46:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:10:19

FDA-CBER-2022-1614-0995970

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
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)	05 Aug 2020 18:12:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:12:09
Data point term sent to Coder	System	05 Aug 2020 18:11:04
User entered 'SEASONAL ALLERGIES'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995971

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'UN UNK 2017'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995972

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995973

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995974

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995975

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995976

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'Jan 2017'	System	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995977

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '2017'	System	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995978

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995979

US3452232
Folder: Screening
Form: Medical History (2)
Generated On: 11 Aug 2021 22:46:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:10:34

FDA-CBER-2022-1614-0995980

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:12:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:12:10
Data point term sent to Coder	System	05 Aug 2020 18:11:05
User entered 'HEARTBURN'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995981

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'UN UNK 2010'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995982

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995983

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995984

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995985

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995986

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'Jan 2010'	System	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995987

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '2010'	System	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995988

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995989

US3452232
Folder: Screening
Form: Medical History (3)
Generated On: 11 Aug 2021 22:46:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:10:48

FDA-CBER-2022-1614-0995990

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:12:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:12:10
Data point term sent to Coder	System	05 Aug 2020 18:11:05
User entered 'BACK PAIN'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995991

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'UN UNK 2015'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995992

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995993

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995994

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995995

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995996

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'Jan 2015'	System	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995997

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '2015'	System	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995998

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0995999

US3452232
Folder: Screening
Form: Medical History (4)
Generated On: 11 Aug 2021 22:46:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:11:01

FDA-CBER-2022-1614-0996000

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:13:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:13:00
Data point term sent to Coder	System	05 Aug 2020 18:12:07
User entered 'MIGRAINES'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:15

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'UN UNK 2017'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:15

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:15

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:15

FDA-CBER-2022-1614-0996004

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:15

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:15

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'Jan 2017'	System	05 Aug 2020 18:11:15

FDA-CBER-2022-1614-0996007

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '2017'	System	05 Aug 2020 18:11:15

FDA-CBER-2022-1614-0996008

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:11:15

FDA-CBER-2022-1614-0996009

US3452232
Folder: Screening
Form: Medical History (5)
Generated On: 11 Aug 2021 22:46:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:11:15

FDA-CBER-2022-1614-0996010

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:13:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:13:00
Data point term sent to Coder	System	05 Aug 2020 18:12:07
User entered 'HEADACHES'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:35

FDA-CBER-2022-1614-0996011

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'UN UNK 2017'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:35

FDA-CBER-2022-1614-0996012

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:35

FDA-CBER-2022-1614-0996013

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:35

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:35

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:35

FDA-CBER-2022-1614-0996016

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'Jan 2017'	System	05 Aug 2020 18:11:35

FDA-CBER-2022-1614-0996017

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '2017'	System	05 Aug 2020 18:11:35

FDA-CBER-2022-1614-0996018

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:11:35

FDA-CBER-2022-1614-0996019

US3452232
Folder: Screening
Form: Medical History (6)
Generated On: 11 Aug 2021 22:46:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:11:35

FDA-CBER-2022-1614-0996020

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:12:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:12:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:07:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:07:16
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:13:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:13:00
Data point term sent to Coder	System	05 Aug 2020 18:12:07
User entered 'ALLERGY TO KEFLEX'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:57

FDA-CBER-2022-1614-0996021

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'UN UNK 1987'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:57

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:57

FDA-CBER-2022-1614-0996023

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:57

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:57

FDA-CBER-2022-1614-0996025

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:11:57

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'Jan 1987'	System	05 Aug 2020 18:11:57

FDA-CBER-2022-1614-0996027

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1987'	System	05 Aug 2020 18:11:57

FDA-CBER-2022-1614-0996028

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:11:57

FDA-CBER-2022-1614-0996029

US3452232
Folder: Screening
Form: Medical History (7)
Generated On: 11 Aug 2021 22:46:20
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	05 Aug 2020 18:11:57

FDA-CBER-2022-1614-0996030

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996031

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996032

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '10:09'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '05 Aug 2020 10:09'	System	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996034

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '68' in	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13
DataPoint set to visible.	System	05 Aug 2020 14:31:27

FDA-CBER-2022-1614-0996035

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '181.4' lb	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13
DataPoint set to visible.	System	05 Aug 2020 14:31:27

FDA-CBER-2022-1614-0996036

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
Amendment Manager: User entered '27.63945'	System	16 Sep 2020 23:43:45
User entered '27.6'	System	17 Aug 2020 19:11:13
DataPoint set to visible.	System	05 Aug 2020 14:31:27

FDA-CBER-2022-1614-0996037

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'kg/m2'	System	17 Aug 2020 19:11:13
DataPoint set to visible.	System	05 Aug 2020 14:31:27

FDA-CBER-2022-1614-0996038

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:09:23
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:57:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:57:05
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 09:45:56
User entered '98.2' F	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996039

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:57:05
User entered 'Oral (Oral)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996040

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996041

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:57:05
User entered '74'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996042

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'bpm'	System	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996043

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:57:05
User entered '14'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996044

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'breaths/min'	System	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996045

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:57:05
User entered '133'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996047

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:57:05
User entered '94'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:13

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US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	17 Aug 2020 19:11:13

FDA-CBER-2022-1614-0996049

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55

FDA-CBER-2022-1614-0996050

US3452232
Folder: Screening
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55

FDA-CBER-2022-1614-0996051

US3452232
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:38

US3452232
Folder: Screening
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 18:17:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 14:22:17
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:38

FDA-CBER-2022-1614-0996053

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

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US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

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US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

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US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

FDA-CBER-2022-1614-0996066

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '1'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

FDA-CBER-2022-1614-0996067

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

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US3452232

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:46:20

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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

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US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20

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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

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US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

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US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '0'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

FDA-CBER-2022-1614-0996073

US3452232
Folder: Screening
Form: Risk of Exposure
Generated On: 11 Aug 2021 22:46:20
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 18:12:24

FDA-CBER-2022-1614-0996074

US3452232
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:56

FDA-CBER-2022-1614-0996075

US3452232
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:56

FDA-CBER-2022-1614-0996076

US3452232
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:31:56

FDA-CBER-2022-1614-0996077

US3452232
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'VISIT1'	System	05 Aug 2020 14:31:56

FDA-CBER-2022-1614-0996078

US3452232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:20
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:29:40

FDA-CBER-2022-1614-0996079

US3452232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:20
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:12:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:12:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 14:29:40
User entered '101225' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:29:40

FDA-CBER-2022-1614-0996080

US3452232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:20
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 14:29:40

FDA-CBER-2022-1614-0996081

US3452232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:20

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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:32:04

US3452232

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:46:20

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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:32:04

US3452232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:20
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:32:04

FDA-CBER-2022-1614-0996084

US3452232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:20
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:32:04

FDA-CBER-2022-1614-0996085

US3452232
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 11 Aug 2021 22:46:20
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:32:04

FDA-CBER-2022-1614-0996086

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:20
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:09:18
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 09:45:27
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996087

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:20
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:20
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:09:18
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 09:45:27
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996089

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:20
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996090

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996091

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996093

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '10:09' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996094

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '05 Aug 2020 10:09'	System	24 Sep 2020 17:58:04
User entered empty.	System	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996095

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '98.2' F reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996096

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996097

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996098

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '74' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996099

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'bpm'	System	24 Sep 2020 17:58:04
User entered empty.	System	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996100

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '14' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996101

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'breaths/min'	System	24 Sep 2020 17:58:04
User entered empty.	System	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996102

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '133' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996103

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	24 Sep 2020 17:58:04
User entered empty.	System	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996104

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '94' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	24 Sep 2020 17:58:04
User entered empty.	System	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996106

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:20
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:09:18
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:11
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 09:45:27
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996107

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 11 Aug 2021 22:46:20
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:58:04
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:11:31

FDA-CBER-2022-1614-0996108

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996109

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996110

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996111

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:12:26
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	17 Aug 2020 19:12:13
User entered '11:16'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996112

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '05 Aug 2020 11:16'	System	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996113

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '98.3' F	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996114

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Oral (Oral)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996115

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996116

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '66'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996117

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'bpm'	System	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996118

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '12'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996119

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'breaths/min'	System	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996120

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '130'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996121

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996122

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '90'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996123

US3452232
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	17 Aug 2020 19:12:13

FDA-CBER-2022-1614-0996124

US3452232
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:32:18

FDA-CBER-2022-1614-0996125

US3452232
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:32:18

FDA-CBER-2022-1614-0996126

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996127

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 15:33:58

US3452232

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:46:20

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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 15:33:58

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996130

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996131

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '10:29'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996132

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '05 Aug 2020 10:29'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996133

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Left Arm (LEFT ARM)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996134

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'ONCE'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996135

US3452232
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996136

US3452232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:42

FDA-CBER-2022-1614-0996137

US3452232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:42

FDA-CBER-2022-1614-0996138

US3452232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '10:13'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:42

FDA-CBER-2022-1614-0996139

US3452232
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '05 Aug 2020 10:13'	System	17 Aug 2020 19:12:42

FDA-CBER-2022-1614-0996140

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:46:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '05 Aug 2020'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:59

FDA-CBER-2022-1614-0996141

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:20
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:59

FDA-CBER-2022-1614-0996142

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:59

FDA-CBER-2022-1614-0996143

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '10:11'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:12:59

FDA-CBER-2022-1614-0996144

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '05 Aug 2020 10:11'	System	17 Aug 2020 19:12:59

FDA-CBER-2022-1614-0996145

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:20
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:13:09

FDA-CBER-2022-1614-0996146

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:13:09

FDA-CBER-2022-1614-0996147

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '10:11'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:13:09

FDA-CBER-2022-1614-0996148

US3452232
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '05 Aug 2020 10:11'	System	17 Aug 2020 19:13:09

FDA-CBER-2022-1614-0996149

US3452232
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	05 Aug 2020 14:32:26

FDA-CBER-2022-1614-0996150

US3452232
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	05 Aug 2020 14:32:26

FDA-CBER-2022-1614-0996151

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996152

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:13:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '81603244-718b-4f07-b7b2-d5057ae59eab'	System	05 Aug 2020 16:13:50
User entered 'Yes (Y)'	System	05 Aug 2020 16:13:50

FDA-CBER-2022-1614-0996153

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:13:34', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '81603244-718b-4f07-b7b2-d5057ae59eab'	System	05 Aug 2020 16:13:50
User entered '98.3'	System	05 Aug 2020 16:13:50

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:13:37', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '81603244-718b-4f07-b7b2-d5057ae59eab'	System	05 Aug 2020 16:13:50
User entered 'No (N)'	System	05 Aug 2020 16:13:50

FDA-CBER-2022-1614-0996155

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:13:46', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '81603244-718b-4f07-b7b2-d5057ae59eab'	System	05 Aug 2020 16:13:50
User entered '05 Aug 2020 11:13'	System	05 Aug 2020 16:13:50

FDA-CBER-2022-1614-0996156

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 10:49'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996157

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 13:19'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996158

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996159

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:01', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd7aae71e-afd9-4d0a-816b-b9f025171518'	System	05 Aug 2020 19:20:11
User entered 'Yes (Y)'	System	05 Aug 2020 19:20:11

FDA-CBER-2022-1614-0996160

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:04', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd7aae71e-afd9-4d0a-816b-b9f025171518'	System	05 Aug 2020 19:20:11
User entered '97.3'	System	05 Aug 2020 19:20:11

FDA-CBER-2022-1614-0996161

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:06', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd7aae71e-afd9-4d0a-816b-b9f025171518'	System	05 Aug 2020 19:20:11
User entered 'No (N)'	System	05 Aug 2020 19:20:11

FDA-CBER-2022-1614-0996162

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:08', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd7aae71e-afd9-4d0a-816b-b9f025171518'	System	05 Aug 2020 19:20:11
User entered '05 Aug 2020 14:20'	System	05 Aug 2020 19:20:11

FDA-CBER-2022-1614-0996163

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996164

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996165

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 2'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996166

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:43:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b0ada231-2ab4-4b11-bb75-48fa75250f4e'	System	06 Aug 2020 17:43:41
User entered 'Yes (Y)'	System	06 Aug 2020 17:43:41

FDA-CBER-2022-1614-0996167

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:43:33', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b0ada231-2ab4-4b11-bb75-48fa75250f4e'	System	06 Aug 2020 17:43:41
User entered '96.5'	System	06 Aug 2020 17:43:41

FDA-CBER-2022-1614-0996168

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:43:35', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b0ada231-2ab4-4b11-bb75-48fa75250f4e'	System	06 Aug 2020 17:43:41
User entered 'No (N)'	System	06 Aug 2020 17:43:41

FDA-CBER-2022-1614-0996169

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:43:38', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b0ada231-2ab4-4b11-bb75-48fa75250f4e'	System	06 Aug 2020 17:43:41
User entered '06 Aug 2020 12:43'	System	06 Aug 2020 17:43:41

FDA-CBER-2022-1614-0996170

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996171

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996172

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 3'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996173

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T22:58:44', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58ded978-aeea-480a-860a-3fc5630616a8'	System	08 Aug 2020 03:58:54
User entered 'Yes (Y)'	System	08 Aug 2020 03:58:54

FDA-CBER-2022-1614-0996174

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T22:58:47', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58ded978-aeea-480a-860a-3fc5630616a8'	System	08 Aug 2020 03:58:54
User entered '96.0'	System	08 Aug 2020 03:58:54

FDA-CBER-2022-1614-0996175

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T22:58:49', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58ded978-aeea-480a-860a-3fc5630616a8'	System	08 Aug 2020 03:58:54
User entered 'No (N)'	System	08 Aug 2020 03:58:54

FDA-CBER-2022-1614-0996176

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T22:58:51', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58ded978-aeea-480a-860a-3fc5630616a8'	System	08 Aug 2020 03:58:54
User entered '07 Aug 2020 22:58'	System	08 Aug 2020 03:58:54

FDA-CBER-2022-1614-0996177

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996178

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996179

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 4'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996180

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:37', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1be4a5f3-3b10-493d-9081-c1cd27d7fc47'	System	08 Aug 2020 18:25:46
User entered 'Yes (Y)'	System	08 Aug 2020 18:25:46

FDA-CBER-2022-1614-0996181

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:39', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1be4a5f3-3b10-493d-9081-c1cd27d7fc47'	System	08 Aug 2020 18:25:46
User entered '97.2'	System	08 Aug 2020 18:25:46

FDA-CBER-2022-1614-0996182

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:41', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1be4a5f3-3b10-493d-9081-c1cd27d7fc47'	System	08 Aug 2020 18:25:46
User entered 'No (N)'	System	08 Aug 2020 18:25:46

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:43', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1be4a5f3-3b10-493d-9081-c1cd27d7fc47'	System	08 Aug 2020 18:25:46
User entered '08 Aug 2020 13:25'	System	08 Aug 2020 18:25:46

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996185

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996186

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 5'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996187

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:42', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '14dc026a-6ee4-48e9-a7ce-aee695de6fe0'	System	10 Aug 2020 00:11:35
User entered 'Yes (Y)'	System	10 Aug 2020 00:11:35

FDA-CBER-2022-1614-0996188

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:11:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '14dc026a-6ee4-48e9-a7ce-aee695de6fe0'	System	10 Aug 2020 00:11:35
User entered '96.7'	System	10 Aug 2020 00:11:35

FDA-CBER-2022-1614-0996189

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:11:29', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '14dc026a-6ee4-48e9-a7ce-aee695de6fe0'	System	10 Aug 2020 00:11:35
User entered 'No (N)'	System	10 Aug 2020 00:11:35

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:11:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '14dc026a-6ee4-48e9-a7ce-aee695de6fe0'	System	10 Aug 2020 00:11:35
User entered '09 Aug 2020 19:11'	System	10 Aug 2020 00:11:35

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996192

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996193

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 6'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996194

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-10T23:59:49', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dd8d813-7b45-4b40-bdb5-b276d2858eed'	System	11 Aug 2020 04:59:58
User entered 'Yes (Y)'	System	11 Aug 2020 04:59:58

FDA-CBER-2022-1614-0996195

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-10T23:59:52', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dd8d813-7b45-4b40-bdb5-b276d2858eed'	System	11 Aug 2020 04:59:58
User entered '98.7'	System	11 Aug 2020 04:59:58

FDA-CBER-2022-1614-0996196

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-10T23:59:54', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dd8d813-7b45-4b40-bdb5-b276d2858eed'	System	11 Aug 2020 04:59:58
User entered 'No (N)'	System	11 Aug 2020 04:59:58

FDA-CBER-2022-1614-0996197

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-10T23:59:56', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dd8d813-7b45-4b40-bdb5-b276d2858eed'	System	11 Aug 2020 04:59:58
User entered '10 Aug 2020 23:59'	System	11 Aug 2020 04:59:58

FDA-CBER-2022-1614-0996198

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996199

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996200

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 7'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996201

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:58', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'a927bff3-e2dc-4d4f-9d56-2dec41be7c5e'	System	11 Aug 2020 20:37:28
User entered 'Yes (Y)'	System	11 Aug 2020 20:37:28

FDA-CBER-2022-1614-0996202

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:37:22', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'a927bff3-e2dc-4d4f-9d56-2dec41be7c5e'	System	11 Aug 2020 20:37:28
User entered '97.9'	System	11 Aug 2020 20:37:28

FDA-CBER-2022-1614-0996203

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:37:24', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'a927bff3-e2dc-4d4f-9d56-2dec41be7c5e'	System	11 Aug 2020 20:37:28
User entered 'No (N)'	System	11 Aug 2020 20:37:28

FDA-CBER-2022-1614-0996204

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:37:27', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'a927bff3-e2dc-4d4f-9d56-2dec41be7c5e'	System	11 Aug 2020 20:37:28
User entered '11 Aug 2020 15:37'	System	11 Aug 2020 20:37:28

FDA-CBER-2022-1614-0996205

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996206

US3452232
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996207

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996208

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:13:59', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9785d1ae-3f5e-45ef-b90a-92d67c88859f'	System	05 Aug 2020 16:14:24
User entered 'None (1)'	System	05 Aug 2020 16:14:24

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:09', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9785d1ae-3f5e-45ef-b90a-92d67c88859f'	System	05 Aug 2020 16:14:24
User entered 'No (N)'	System	05 Aug 2020 16:14:24

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9785d1ae-3f5e-45ef-b90a-92d67c88859f'	System	05 Aug 2020 16:14:24
User entered 'No (N)'	System	05 Aug 2020 16:14:24

FDA-CBER-2022-1614-0996211

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:20', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9785d1ae-3f5e-45ef-b90a-92d67c88859f'	System	05 Aug 2020 16:14:24
User entered 'None (1)'	System	05 Aug 2020 16:14:24

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:23', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9785d1ae-3f5e-45ef-b90a-92d67c88859f'	System	05 Aug 2020 16:14:24
User entered '05 Aug 2020 11:14'	System	05 Aug 2020 16:14:24

FDA-CBER-2022-1614-0996213

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 10:49'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996214

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 13:19'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996215

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996216

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ebf8b6fd-bcd6-456c-9516-46e5e3a05469'	System	05 Aug 2020 19:20:23
User entered 'None (1)'	System	05 Aug 2020 19:20:23

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:13', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ebf8b6fd-bcd6-456c-9516-46e5e3a05469'	System	05 Aug 2020 19:20:23
User entered 'No (N)'	System	05 Aug 2020 19:20:23

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:15', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ebf8b6fd-bcd6-456c-9516-46e5e3a05469'	System	05 Aug 2020 19:20:23
User entered 'No (N)'	System	05 Aug 2020 19:20:23

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ebf8b6fd-bcd6-456c-9516-46e5e3a05469'	System	05 Aug 2020 19:20:23
User entered 'None (1)'	System	05 Aug 2020 19:20:23

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:18', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ebf8b6fd-bcd6-456c-9516-46e5e3a05469'	System	05 Aug 2020 19:20:23
User entered '05 Aug 2020 14:20'	System	05 Aug 2020 19:20:23

FDA-CBER-2022-1614-0996221

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996222

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996223

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 2'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996224

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0b28427-78ae-4d24-9c1b-e4695811c845'	System	06 Aug 2020 17:04:45
User entered 'None (1)'	System	06 Aug 2020 17:04:45

FDA-CBER-2022-1614-0996225

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:33', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0b28427-78ae-4d24-9c1b-e4695811c845'	System	06 Aug 2020 17:04:45
User entered 'No (N)'	System	06 Aug 2020 17:04:45

FDA-CBER-2022-1614-0996226

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:35', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0b28427-78ae-4d24-9c1b-e4695811c845'	System	06 Aug 2020 17:04:45
User entered 'No (N)'	System	06 Aug 2020 17:04:45

FDA-CBER-2022-1614-0996227

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:40', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0b28427-78ae-4d24-9c1b-e4695811c845'	System	06 Aug 2020 17:04:45
User entered 'None (1)'	System	06 Aug 2020 17:04:45

FDA-CBER-2022-1614-0996228

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:42', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0b28427-78ae-4d24-9c1b-e4695811c845'	System	06 Aug 2020 17:04:45
User entered '06 Aug 2020 12:04'	System	06 Aug 2020 17:04:45

FDA-CBER-2022-1614-0996229

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996230

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996231

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 3'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996232

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:14', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3753792b-fc4b-4c42-aab3-3892f1c53cf9'	System	07 Aug 2020 23:07:24
User entered 'None (1)'	System	07 Aug 2020 23:07:24

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3753792b-fc4b-4c42-aab3-3892f1c53cf9'	System	07 Aug 2020 23:07:24
User entered 'No (N)'	System	07 Aug 2020 23:07:24

FDA-CBER-2022-1614-0996234

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:18', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3753792b-fc4b-4c42-aab3-3892f1c53cf9'	System	07 Aug 2020 23:07:24
User entered 'No (N)'	System	07 Aug 2020 23:07:24

FDA-CBER-2022-1614-0996235

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:20', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3753792b-fc4b-4c42-aab3-3892f1c53cf9'	System	07 Aug 2020 23:07:24
User entered 'None (1)'	System	07 Aug 2020 23:07:24

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:22', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3753792b-fc4b-4c42-aab3-3892f1c53cf9'	System	07 Aug 2020 23:07:24
User entered '07 Aug 2020 18:07'	System	07 Aug 2020 23:07:24

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996238

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996239

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 4'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996240

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:46', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c736f9ac-7c69-4f52-af0b-3b0a03ec297c'	System	08 Aug 2020 18:25:57
User entered 'None (1)'	System	08 Aug 2020 18:25:57

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:47', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c736f9ac-7c69-4f52-af0b-3b0a03ec297c'	System	08 Aug 2020 18:25:57
User entered 'No (N)'	System	08 Aug 2020 18:25:57

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:50', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c736f9ac-7c69-4f52-af0b-3b0a03ec297c'	System	08 Aug 2020 18:25:57
User entered 'No (N)'	System	08 Aug 2020 18:25:57

FDA-CBER-2022-1614-0996243

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:52', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c736f9ac-7c69-4f52-af0b-3b0a03ec297c'	System	08 Aug 2020 18:25:57
User entered 'None (1)'	System	08 Aug 2020 18:25:57

FDA-CBER-2022-1614-0996244

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:54', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c736f9ac-7c69-4f52-af0b-3b0a03ec297c'	System	08 Aug 2020 18:25:57
User entered '08 Aug 2020 13:25'	System	08 Aug 2020 18:25:57

FDA-CBER-2022-1614-0996245

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996246

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996247

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 5'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996248

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:09:59', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '17bab624-8135-4362-8b2f-72cfff3597a9'	System	10 Aug 2020 00:10:15
User entered 'None (1)'	System	10 Aug 2020 00:10:15

FDA-CBER-2022-1614-0996249

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:00', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '17bab624-8135-4362-8b2f-72cfff3597a9'	System	10 Aug 2020 00:10:15
User entered 'No (N)'	System	10 Aug 2020 00:10:15

FDA-CBER-2022-1614-0996250

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:02', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '17bab624-8135-4362-8b2f-72cfff3597a9'	System	10 Aug 2020 00:10:15
User entered 'No (N)'	System	10 Aug 2020 00:10:15

FDA-CBER-2022-1614-0996251

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:03', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '17bab624-8135-4362-8b2f-72cfff3597a9'	System	10 Aug 2020 00:10:15
User entered 'None (1)'	System	10 Aug 2020 00:10:15

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:14', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '17bab624-8135-4362-8b2f-72cfff3597a9'	System	10 Aug 2020 00:10:15
User entered '09 Aug 2020 19:10'	System	10 Aug 2020 00:10:15

FDA-CBER-2022-1614-0996253

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996254

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996255

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 6'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996256

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-10T23:59:58', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'bc745be4-5017-4d36-b42e-8e3f1a1db716'	System	11 Aug 2020 05:00:06
User entered 'None (1)'	System	11 Aug 2020 05:00:06

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:00', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'bc745be4-5017-4d36-b42e-8e3f1a1db716'	System	11 Aug 2020 05:00:06
User entered 'No (N)'	System	11 Aug 2020 05:00:06

FDA-CBER-2022-1614-0996258

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:01', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'bc745be4-5017-4d36-b42e-8e3f1a1db716'	System	11 Aug 2020 05:00:06
User entered 'No (N)'	System	11 Aug 2020 05:00:06

FDA-CBER-2022-1614-0996259

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:02', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'bc745be4-5017-4d36-b42e-8e3f1a1db716'	System	11 Aug 2020 05:00:06
User entered 'None (1)'	System	11 Aug 2020 05:00:06

FDA-CBER-2022-1614-0996260

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:04', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'bc745be4-5017-4d36-b42e-8e3f1a1db716'	System	11 Aug 2020 05:00:06
User entered '11 Aug 2020 00:00'	System	11 Aug 2020 05:00:06

FDA-CBER-2022-1614-0996261

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996262

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996263

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 7'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996264

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:47', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3b408567-55ba-4a33-99d6-5793f966e9c0'	System	11 Aug 2020 20:36:56
User entered 'None (1)'	System	11 Aug 2020 20:36:56

FDA-CBER-2022-1614-0996265

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:48', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3b408567-55ba-4a33-99d6-5793f966e9c0'	System	11 Aug 2020 20:36:56
User entered 'No (N)'	System	11 Aug 2020 20:36:56

FDA-CBER-2022-1614-0996266

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:50', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3b408567-55ba-4a33-99d6-5793f966e9c0'	System	11 Aug 2020 20:36:56
User entered 'No (N)'	System	11 Aug 2020 20:36:56

FDA-CBER-2022-1614-0996267

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:52', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3b408567-55ba-4a33-99d6-5793f966e9c0'	System	11 Aug 2020 20:36:56
User entered 'None (1)'	System	11 Aug 2020 20:36:56

FDA-CBER-2022-1614-0996268

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:54', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3b408567-55ba-4a33-99d6-5793f966e9c0'	System	11 Aug 2020 20:36:56
User entered '11 Aug 2020 15:36'	System	11 Aug 2020 20:36:56

FDA-CBER-2022-1614-0996269

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996270

US3452232
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996271

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996272

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '7b339ee4-878b-45df-8cce-727066de365e'	System	05 Aug 2020 16:14:55
User entered 'None (0)'	System	05 Aug 2020 16:14:55

FDA-CBER-2022-1614-0996273

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:34', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '7b339ee4-878b-45df-8cce-727066de365e'	System	05 Aug 2020 16:14:55
User entered 'None (0)'	System	05 Aug 2020 16:14:55

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:37', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '7b339ee4-878b-45df-8cce-727066de365e'	System	05 Aug 2020 16:14:55
User entered 'None (0)'	System	05 Aug 2020 16:14:55

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:39', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '7b339ee4-878b-45df-8cce-727066de365e'	System	05 Aug 2020 16:14:55
User entered 'None (0)'	System	05 Aug 2020 16:14:55

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:41', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '7b339ee4-878b-45df-8cce-727066de365e'	System	05 Aug 2020 16:14:55
User entered 'None (0)'	System	05 Aug 2020 16:14:55

FDA-CBER-2022-1614-0996277

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:45', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '7b339ee4-878b-45df-8cce-727066de365e'	System	05 Aug 2020 16:14:55
User entered 'None (0)'	System	05 Aug 2020 16:14:55

FDA-CBER-2022-1614-0996278

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:50', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '7b339ee4-878b-45df-8cce-727066de365e'	System	05 Aug 2020 16:14:55
User entered 'No (N)'	System	05 Aug 2020 16:14:55

FDA-CBER-2022-1614-0996279

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T11:14:52', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '7b339ee4-878b-45df-8cce-727066de365e'	System	05 Aug 2020 16:14:55
User entered '05 Aug 2020 11:14'	System	05 Aug 2020 16:14:55

FDA-CBER-2022-1614-0996280

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 10:49'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996281

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 13:19'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996282

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996283

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:23', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dfccbf83-f381-4c58-b42c-7a017aaf1f9b'	System	05 Aug 2020 19:20:39
User entered 'None (0)'	System	05 Aug 2020 19:20:39

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:24', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dfccbf83-f381-4c58-b42c-7a017aaf1f9b'	System	05 Aug 2020 19:20:39
User entered 'None (0)'	System	05 Aug 2020 19:20:39

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dfccbf83-f381-4c58-b42c-7a017aaf1f9b'	System	05 Aug 2020 19:20:39
User entered 'None (0)'	System	05 Aug 2020 19:20:39

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:27', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dfccbf83-f381-4c58-b42c-7a017aaf1f9b'	System	05 Aug 2020 19:20:39
User entered 'None (0)'	System	05 Aug 2020 19:20:39

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dfccbf83-f381-4c58-b42c-7a017aaf1f9b'	System	05 Aug 2020 19:20:39
User entered 'None (0)'	System	05 Aug 2020 19:20:39

FDA-CBER-2022-1614-0996288

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:30', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dfccbf83-f381-4c58-b42c-7a017aaf1f9b'	System	05 Aug 2020 19:20:39
User entered 'None (0)'	System	05 Aug 2020 19:20:39

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:33', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dfccbf83-f381-4c58-b42c-7a017aaf1f9b'	System	05 Aug 2020 19:20:39
User entered 'No (N)'	System	05 Aug 2020 19:20:39

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-05T14:20:35', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dfccbf83-f381-4c58-b42c-7a017aaf1f9b'	System	05 Aug 2020 19:20:39
User entered '05 Aug 2020 14:20'	System	05 Aug 2020 19:20:39

FDA-CBER-2022-1614-0996291

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '05 Aug 2020 14:14'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996292

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996293

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 2'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996294

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:46', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dbf31c45-7c6a-41a8-8321-ece41e2fc3ec'	System	06 Aug 2020 17:05:02
User entered 'None (0)'	System	06 Aug 2020 17:05:02

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:48', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dbf31c45-7c6a-41a8-8321-ece41e2fc3ec'	System	06 Aug 2020 17:05:02
User entered 'None (0)'	System	06 Aug 2020 17:05:02

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:50', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dbf31c45-7c6a-41a8-8321-ece41e2fc3ec'	System	06 Aug 2020 17:05:02
User entered 'None (0)'	System	06 Aug 2020 17:05:02

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:51', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dbf31c45-7c6a-41a8-8321-ece41e2fc3ec'	System	06 Aug 2020 17:05:02
User entered 'None (0)'	System	06 Aug 2020 17:05:02

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:53', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dbf31c45-7c6a-41a8-8321-ece41e2fc3ec'	System	06 Aug 2020 17:05:02
User entered 'None (0)'	System	06 Aug 2020 17:05:02

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:54', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dbf31c45-7c6a-41a8-8321-ece41e2fc3ec'	System	06 Aug 2020 17:05:02
User entered 'None (0)'	System	06 Aug 2020 17:05:02

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:56', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dbf31c45-7c6a-41a8-8321-ece41e2fc3ec'	System	06 Aug 2020 17:05:02
User entered 'No (N)'	System	06 Aug 2020 17:05:02

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-06T12:04:58', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'dbf31c45-7c6a-41a8-8321-ece41e2fc3ec'	System	06 Aug 2020 17:05:02
User entered '06 Aug 2020 12:04'	System	06 Aug 2020 17:05:02

FDA-CBER-2022-1614-0996302

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996303

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996304

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 3'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996305

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:25', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dac6a22-136f-4196-9144-98162531a6da'	System	07 Aug 2020 23:07:38
User entered 'None (0)'	System	07 Aug 2020 23:07:38

FDA-CBER-2022-1614-0996306

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dac6a22-136f-4196-9144-98162531a6da'	System	07 Aug 2020 23:07:38
User entered 'None (0)'	System	07 Aug 2020 23:07:38

FDA-CBER-2022-1614-0996307

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dac6a22-136f-4196-9144-98162531a6da'	System	07 Aug 2020 23:07:38
User entered 'None (0)'	System	07 Aug 2020 23:07:38

FDA-CBER-2022-1614-0996308

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:29', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dac6a22-136f-4196-9144-98162531a6da'	System	07 Aug 2020 23:07:38
User entered 'None (0)'	System	07 Aug 2020 23:07:38

FDA-CBER-2022-1614-0996309

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:30', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dac6a22-136f-4196-9144-98162531a6da'	System	07 Aug 2020 23:07:38
User entered 'None (0)'	System	07 Aug 2020 23:07:38

FDA-CBER-2022-1614-0996310

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dac6a22-136f-4196-9144-98162531a6da'	System	07 Aug 2020 23:07:38
User entered 'None (0)'	System	07 Aug 2020 23:07:38

FDA-CBER-2022-1614-0996311

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:34', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dac6a22-136f-4196-9144-98162531a6da'	System	07 Aug 2020 23:07:38
User entered 'No (N)'	System	07 Aug 2020 23:07:38

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-07T18:07:36', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3dac6a22-136f-4196-9144-98162531a6da'	System	07 Aug 2020 23:07:38
User entered '07 Aug 2020 18:07'	System	07 Aug 2020 23:07:38

FDA-CBER-2022-1614-0996313

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996314

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996315

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 4'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996316

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:25:59', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd3c5f9d4-6a64-4722-acfb-6d6f5f5851c9'	System	08 Aug 2020 18:26:17
User entered 'None (0)'	System	08 Aug 2020 18:26:17

FDA-CBER-2022-1614-0996317

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:26:01', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd3c5f9d4-6a64-4722-acfb-6d6f5f5851c9'	System	08 Aug 2020 18:26:17
User entered 'None (0)'	System	08 Aug 2020 18:26:17

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:26:04', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd3c5f9d4-6a64-4722-acfb-6d6f5f5851c9'	System	08 Aug 2020 18:26:17
User entered 'None (0)'	System	08 Aug 2020 18:26:17

FDA-CBER-2022-1614-0996319

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:26:05', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd3c5f9d4-6a64-4722-acfb-6d6f5f5851c9'	System	08 Aug 2020 18:26:17
User entered 'None (0)'	System	08 Aug 2020 18:26:17

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:26:07', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd3c5f9d4-6a64-4722-acfb-6d6f5f5851c9'	System	08 Aug 2020 18:26:17
User entered 'None (0)'	System	08 Aug 2020 18:26:17

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:26:08', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd3c5f9d4-6a64-4722-acfb-6d6f5f5851c9'	System	08 Aug 2020 18:26:17
User entered 'None (0)'	System	08 Aug 2020 18:26:17

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:26:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd3c5f9d4-6a64-4722-acfb-6d6f5f5851c9'	System	08 Aug 2020 18:26:17
User entered 'No (N)'	System	08 Aug 2020 18:26:17

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-08T13:26:13', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd3c5f9d4-6a64-4722-acfb-6d6f5f5851c9'	System	08 Aug 2020 18:26:17
User entered '08 Aug 2020 13:26'	System	08 Aug 2020 18:26:17

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996325

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996326

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 5'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996327

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:22', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ac3fd088-8313-4e83-80b3-4b05b701cde0'	System	10 Aug 2020 00:10:41
User entered 'None (0)'	System	10 Aug 2020 00:10:41

FDA-CBER-2022-1614-0996328

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:24', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ac3fd088-8313-4e83-80b3-4b05b701cde0'	System	10 Aug 2020 00:10:41
User entered 'None (0)'	System	10 Aug 2020 00:10:41

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:25', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ac3fd088-8313-4e83-80b3-4b05b701cde0'	System	10 Aug 2020 00:10:41
User entered 'None (0)'	System	10 Aug 2020 00:10:41

FDA-CBER-2022-1614-0996330

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ac3fd088-8313-4e83-80b3-4b05b701cde0'	System	10 Aug 2020 00:10:41
User entered 'None (0)'	System	10 Aug 2020 00:10:41

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ac3fd088-8313-4e83-80b3-4b05b701cde0'	System	10 Aug 2020 00:10:41
User entered 'None (0)'	System	10 Aug 2020 00:10:41

FDA-CBER-2022-1614-0996332

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:29', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ac3fd088-8313-4e83-80b3-4b05b701cde0'	System	10 Aug 2020 00:10:41
User entered 'None (0)'	System	10 Aug 2020 00:10:41

FDA-CBER-2022-1614-0996333

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:36', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ac3fd088-8313-4e83-80b3-4b05b701cde0'	System	10 Aug 2020 00:10:41
User entered 'No (N)'	System	10 Aug 2020 00:10:41

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-09T19:10:38', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ac3fd088-8313-4e83-80b3-4b05b701cde0'	System	10 Aug 2020 00:10:41
User entered '09 Aug 2020 19:10'	System	10 Aug 2020 00:10:41

FDA-CBER-2022-1614-0996335

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996336

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996337

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 6'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996338

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:07', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8517fc89-fd2a-4917-ab0c-b62827f20760'	System	11 Aug 2020 05:00:19
User entered 'None (0)'	System	11 Aug 2020 05:00:19

FDA-CBER-2022-1614-0996339

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:09', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8517fc89-fd2a-4917-ab0c-b62827f20760'	System	11 Aug 2020 05:00:19
User entered 'None (0)'	System	11 Aug 2020 05:00:19

FDA-CBER-2022-1614-0996340

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:10', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8517fc89-fd2a-4917-ab0c-b62827f20760'	System	11 Aug 2020 05:00:19
User entered 'None (0)'	System	11 Aug 2020 05:00:19

FDA-CBER-2022-1614-0996341

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8517fc89-fd2a-4917-ab0c-b62827f20760'	System	11 Aug 2020 05:00:19
User entered 'None (0)'	System	11 Aug 2020 05:00:19

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:13', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8517fc89-fd2a-4917-ab0c-b62827f20760'	System	11 Aug 2020 05:00:19
User entered 'None (0)'	System	11 Aug 2020 05:00:19

FDA-CBER-2022-1614-0996343

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:14', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8517fc89-fd2a-4917-ab0c-b62827f20760'	System	11 Aug 2020 05:00:19
User entered 'None (0)'	System	11 Aug 2020 05:00:19

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:15', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8517fc89-fd2a-4917-ab0c-b62827f20760'	System	11 Aug 2020 05:00:19
User entered 'No (N)'	System	11 Aug 2020 05:00:19

FDA-CBER-2022-1614-0996345

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T00:00:17', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8517fc89-fd2a-4917-ab0c-b62827f20760'	System	11 Aug 2020 05:00:19
User entered '11 Aug 2020 00:00'	System	11 Aug 2020 05:00:19

FDA-CBER-2022-1614-0996346

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996347

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996348

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 7'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996349

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5ee5374a-7ac2-43e3-a38e-ba27063fd8f2'	System	11 Aug 2020 20:36:44
User entered 'None (0)'	System	11 Aug 2020 20:36:44

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:29', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5ee5374a-7ac2-43e3-a38e-ba27063fd8f2'	System	11 Aug 2020 20:36:44
User entered 'None (0)'	System	11 Aug 2020 20:36:44

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:32', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5ee5374a-7ac2-43e3-a38e-ba27063fd8f2'	System	11 Aug 2020 20:36:44
User entered 'None (0)'	System	11 Aug 2020 20:36:44

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:33', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5ee5374a-7ac2-43e3-a38e-ba27063fd8f2'	System	11 Aug 2020 20:36:44
User entered 'None (0)'	System	11 Aug 2020 20:36:44

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:36', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5ee5374a-7ac2-43e3-a38e-ba27063fd8f2'	System	11 Aug 2020 20:36:44
User entered 'None (0)'	System	11 Aug 2020 20:36:44

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:38', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5ee5374a-7ac2-43e3-a38e-ba27063fd8f2'	System	11 Aug 2020 20:36:44
User entered 'None (0)'	System	11 Aug 2020 20:36:44

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:40', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5ee5374a-7ac2-43e3-a38e-ba27063fd8f2'	System	11 Aug 2020 20:36:44
User entered 'No (N)'	System	11 Aug 2020 20:36:44

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-08-11T15:36:42', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5ee5374a-7ac2-43e3-a38e-ba27063fd8f2'	System	11 Aug 2020 20:36:44
User entered '11 Aug 2020 15:36'	System	11 Aug 2020 20:36:44

FDA-CBER-2022-1614-0996357

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996358

US3452232
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996359

US3452232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	12 Aug 2020 20:41:54

US3452232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '12 Aug 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	12 Aug 2020 20:41:54

US3452232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Contact Made (CONTACT MADE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	12 Aug 2020 20:41:54

US3452232
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	12 Aug 2020 20:41:54

FDA-CBER-2022-1614-0996363

US3452232
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	12 Aug 2020 20:42:00

US3452232
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	12 Aug 2020 20:42:00

FDA-CBER-2022-1614-0996365

US3452232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Aug 2020 14:00:55

FDA-CBER-2022-1614-0996366

US3452232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered '19 Aug 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Aug 2020 14:00:55

US3452232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Contact Made (CONTACT MADE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Aug 2020 14:00:55

US3452232
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Aug 2020 14:00:55

FDA-CBER-2022-1614-0996369

US3452232
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Aug 2020 14:01:01

US3452232
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	19 Aug 2020 14:01:01

FDA-CBER-2022-1614-0996371

US3452232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Sep 2020 14:21:10

US3452232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered '26 Aug 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Sep 2020 14:21:10

US3452232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Contact Made (CONTACT MADE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Sep 2020 14:21:10

US3452232
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Sep 2020 14:21:10

FDA-CBER-2022-1614-0996375

US3452232
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:21:50

US3452232
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	08 Sep 2020 14:21:50

FDA-CBER-2022-1614-0996377

US3452232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:22:17

FDA-CBER-2022-1614-0996378

US3452232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '08 Sep 2020'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:22:17

FDA-CBER-2022-1614-0996379

US3452232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:22:17

FDA-CBER-2022-1614-0996380

US3452232
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'VISIT2'	System	08 Sep 2020 14:22:17

FDA-CBER-2022-1614-0996381

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996382

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996383

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '08 Sep 2020'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996384

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '09:16'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996385

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '08 Sep 2020 09:16'	System	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996386

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '98.2' F	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996387

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Oral (Oral)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996388

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996389

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '67'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996390

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'bpm'	System	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996391

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '16'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996392

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'breaths/min'	System	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996393

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '133'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996395

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '88'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996396

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	08 Sep 2020 14:38:21

FDA-CBER-2022-1614-0996397

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996398

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996399

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '08 Sep 2020'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996400

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	24 Sep 2020 17:59:26
User entered '10:05' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	24 Sep 2020 17:59:26
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	23 Sep 2020 21:11:26
User entered '09:05' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Sep 2020 21:11:26
User entered '09:59'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996401

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '08 Sep 2020 10:05'	System	24 Sep 2020 17:59:26
User entered '08 Sep 2020 09:05'	System	23 Sep 2020 21:11:26
User entered '08 Sep 2020 09:59'	System	08 Sep 2020 15:54:04

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '98.5' F	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996403

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Oral (Oral)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996404

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996405

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '59'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996406

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'bpm'	System	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996407

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '14'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996408

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'breaths/min'	System	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996409

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '128'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996410

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996411

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '86'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996412

US3452232
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'mmHg'	System	08 Sep 2020 15:54:04

FDA-CBER-2022-1614-0996413

US3452232
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:31

FDA-CBER-2022-1614-0996414

US3452232
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '08 Sep 2020'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:31

FDA-CBER-2022-1614-0996415

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996416

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996417

US3452232

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:46:20

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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:55

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996419

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '08 Sep 2020'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996420

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '09:29'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996421

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '08 Sep 2020 09:29'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996422

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Left Arm (LEFT ARM)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996423

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'ONCE'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996424

US3452232
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 11 Aug 2021 22:46:20
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996425

US3452232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:10

FDA-CBER-2022-1614-0996426

US3452232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '08 Sep 2020'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:10

FDA-CBER-2022-1614-0996427

US3452232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '09:18'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:10

FDA-CBER-2022-1614-0996428

US3452232
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '08 Sep 2020 09:18'	System	08 Sep 2020 14:39:10

FDA-CBER-2022-1614-0996429

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 11 Aug 2021 22:46:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '08 Sep 2020'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:29

FDA-CBER-2022-1614-0996430

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:20
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:29

FDA-CBER-2022-1614-0996431

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:29

FDA-CBER-2022-1614-0996432

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '09:20'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:29

FDA-CBER-2022-1614-0996433

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 11 Aug 2021 22:46:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '08 Sep 2020 09:20'	System	08 Sep 2020 14:39:29

FDA-CBER-2022-1614-0996434

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:20
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:29

FDA-CBER-2022-1614-0996435

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	09 Oct 2020 21:10:27
User entered 'No (N)' reason for change: Data Entry Error	Kim Hamilton (b) (4)	09 Oct 2020 15:10:31
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:29

FDA-CBER-2022-1614-0996436

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:20
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '09:20' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	09 Oct 2020 21:10:27
User entered empty; reason for change Data Entry Error	Kim Hamilton (b) (4)	09 Oct 2020 15:10:31
User entered '09:20'	Kim Calloway (b) (4) (b) (4)	08 Sep 2020 14:39:29

FDA-CBER-2022-1614-0996437

US3452232
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 11 Aug 2021 22:46:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '08 Sep 2020 09:20'	System	09 Oct 2020 21:10:27
User entered empty.	System	09 Oct 2020 15:10:31
User entered '08 Sep 2020 09:20'	System	08 Sep 2020 14:39:29

US3452232
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Sep 2020 13:24:56

FDA-CBER-2022-1614-0996439

US3452232
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	15 Sep 2020 13:24:56

FDA-CBER-2022-1614-0996440

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996441

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:04:35', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b3f1b4be-fa2b-491f-ae84-c789f1896089'	System	08 Sep 2020 15:04:48
User entered 'Yes (Y)'	System	08 Sep 2020 15:04:48

FDA-CBER-2022-1614-0996442

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:04:40', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b3f1b4be-fa2b-491f-ae84-c789f1896089'	System	08 Sep 2020 15:04:48
User entered '98.5'	System	08 Sep 2020 15:04:48

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:04:42', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b3f1b4be-fa2b-491f-ae84-c789f1896089'	System	08 Sep 2020 15:04:48
User entered 'No (N)'	System	08 Sep 2020 15:04:48

FDA-CBER-2022-1614-0996444

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:04:45', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b3f1b4be-fa2b-491f-ae84-c789f1896089'	System	08 Sep 2020 15:04:48
User entered '08 Sep 2020 10:04'	System	08 Sep 2020 15:04:48

FDA-CBER-2022-1614-0996445

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 09:49'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996446

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 12:19'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996447

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996448

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:20', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '07881666-13b7-4182-9398-829c8dda773c'	System	09 Sep 2020 00:08:37
User entered 'Yes (Y)'	System	09 Sep 2020 00:08:37

FDA-CBER-2022-1614-0996449

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '07881666-13b7-4182-9398-829c8dda773c'	System	09 Sep 2020 00:08:37
User entered '98.9'	System	09 Sep 2020 00:08:37

FDA-CBER-2022-1614-0996450

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '07881666-13b7-4182-9398-829c8dda773c'	System	09 Sep 2020 00:08:37
User entered 'No (N)'	System	09 Sep 2020 00:08:37

FDA-CBER-2022-1614-0996451

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:29', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '07881666-13b7-4182-9398-829c8dda773c'	System	09 Sep 2020 00:08:37
User entered '08 Sep 2020 19:08'	System	09 Sep 2020 00:08:37

FDA-CBER-2022-1614-0996452

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 13:14'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996453

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996454

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 2'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996455

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:19:20', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd873f624-351f-4128-829c-25ec5b46486d'	System	09 Sep 2020 22:20:26
User entered 'Yes (Y)'	System	09 Sep 2020 22:20:26

FDA-CBER-2022-1614-0996456

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:20:18', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd873f624-351f-4128-829c-25ec5b46486d'	System	09 Sep 2020 22:20:26
User entered '98.9'	System	09 Sep 2020 22:20:26

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:20:21', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd873f624-351f-4128-829c-25ec5b46486d'	System	09 Sep 2020 22:20:26
User entered 'No (N)'	System	09 Sep 2020 22:20:26

FDA-CBER-2022-1614-0996458

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:20:23', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'd873f624-351f-4128-829c-25ec5b46486d'	System	09 Sep 2020 22:20:26
User entered '09 Sep 2020 17:20'	System	09 Sep 2020 22:20:26

FDA-CBER-2022-1614-0996459

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996460

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996461

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 3'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996462

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:47', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'f6ca787a-0e45-483a-beca-9cc27030c057'	System	10 Sep 2020 17:20:34
User entered 'Yes (Y)'	System	10 Sep 2020 17:20:34

FDA-CBER-2022-1614-0996463

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:20:24', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'f6ca787a-0e45-483a-beca-9cc27030c057'	System	10 Sep 2020 17:20:34
User entered '98.3'	System	10 Sep 2020 17:20:34

FDA-CBER-2022-1614-0996464

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:20:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'f6ca787a-0e45-483a-beca-9cc27030c057'	System	10 Sep 2020 17:20:34
User entered 'No (N)'	System	10 Sep 2020 17:20:34

FDA-CBER-2022-1614-0996465

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:20:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'f6ca787a-0e45-483a-beca-9cc27030c057'	System	10 Sep 2020 17:20:34
User entered '10 Sep 2020 12:20'	System	10 Sep 2020 17:20:34

FDA-CBER-2022-1614-0996466

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996467

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996468

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 4'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996469

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:52:22', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '783b278f-012b-478a-8d71-f77bc0a1f4d6'	System	12 Sep 2020 12:52:37
User entered 'Yes (Y)'	System	12 Sep 2020 12:52:37

FDA-CBER-2022-1614-0996470

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:52:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '783b278f-012b-478a-8d71-f77bc0a1f4d6'	System	12 Sep 2020 12:52:37
User entered '98.9'	System	12 Sep 2020 12:52:37

FDA-CBER-2022-1614-0996471

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:52:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '783b278f-012b-478a-8d71-f77bc0a1f4d6'	System	12 Sep 2020 12:52:37
User entered 'No (N)'	System	12 Sep 2020 12:52:37

FDA-CBER-2022-1614-0996472

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:52:35', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '783b278f-012b-478a-8d71-f77bc0a1f4d6'	System	12 Sep 2020 12:52:37
User entered '12 Sep 2020 07:52'	System	12 Sep 2020 12:52:37

FDA-CBER-2022-1614-0996473

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996474

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996475

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 5'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996476

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:58:58', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3f7646be-b71c-4548-b43d-4398fcba66fa'	System	13 Sep 2020 13:59:13
User entered 'Yes (Y)'	System	13 Sep 2020 13:59:13

FDA-CBER-2022-1614-0996477

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:59:01', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3f7646be-b71c-4548-b43d-4398fcba66fa'	System	13 Sep 2020 13:59:13
User entered '96.9'	System	13 Sep 2020 13:59:13

FDA-CBER-2022-1614-0996478

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:59:02', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3f7646be-b71c-4548-b43d-4398fcba66fa'	System	13 Sep 2020 13:59:13
User entered 'No (N)'	System	13 Sep 2020 13:59:13

FDA-CBER-2022-1614-0996479

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:59:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '3f7646be-b71c-4548-b43d-4398fcba66fa'	System	13 Sep 2020 13:59:13
User entered '13 Sep 2020 08:59'	System	13 Sep 2020 13:59:13

FDA-CBER-2022-1614-0996480

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996481

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996482

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 6'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996483

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c185e9df-951e-4e55-84b1-75a10e98259e'	System	13 Sep 2020 17:02:15
User entered 'Yes (Y)'	System	13 Sep 2020 17:02:15

FDA-CBER-2022-1614-0996484

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c185e9df-951e-4e55-84b1-75a10e98259e'	System	13 Sep 2020 17:02:15
User entered '97.2'	System	13 Sep 2020 17:02:15

FDA-CBER-2022-1614-0996485

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:33', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c185e9df-951e-4e55-84b1-75a10e98259e'	System	13 Sep 2020 17:02:15
User entered 'No (N)'	System	13 Sep 2020 17:02:15

FDA-CBER-2022-1614-0996486

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:34', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c185e9df-951e-4e55-84b1-75a10e98259e'	System	13 Sep 2020 17:02:15
User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:15

FDA-CBER-2022-1614-0996487

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996488

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996489

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 7'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996490

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:44', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fc720c6a-1d3b-4d56-a940-ae0b2627643c'	System	15 Sep 2020 10:59:57
User entered 'Yes (Y)'	System	15 Sep 2020 10:59:57

FDA-CBER-2022-1614-0996491

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:49', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fc720c6a-1d3b-4d56-a940-ae0b2627643c'	System	15 Sep 2020 10:59:57
User entered '96.9'	System	15 Sep 2020 10:59:57

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:51', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fc720c6a-1d3b-4d56-a940-ae0b2627643c'	System	15 Sep 2020 10:59:57
User entered 'No (N)'	System	15 Sep 2020 10:59:57

FDA-CBER-2022-1614-0996493

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:53', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fc720c6a-1d3b-4d56-a940-ae0b2627643c'	System	15 Sep 2020 10:59:57
User entered '15 Sep 2020 05:59'	System	15 Sep 2020 10:59:57

FDA-CBER-2022-1614-0996494

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996495

US3452232
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996496

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996497

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:04:51', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5cf9ebc3-0503-4c68-95b3-f12100b73c7b'	System	08 Sep 2020 15:05:22
User entered 'None (1)'	System	08 Sep 2020 15:05:22

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:09', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5cf9ebc3-0503-4c68-95b3-f12100b73c7b'	System	08 Sep 2020 15:05:22
User entered 'No (N)'	System	08 Sep 2020 15:05:22

FDA-CBER-2022-1614-0996499

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5cf9ebc3-0503-4c68-95b3-f12100b73c7b'	System	08 Sep 2020 15:05:22
User entered 'No (N)'	System	08 Sep 2020 15:05:22

FDA-CBER-2022-1614-0996500

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:17', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5cf9ebc3-0503-4c68-95b3-f12100b73c7b'	System	08 Sep 2020 15:05:22
User entered 'None (1)'	System	08 Sep 2020 15:05:22

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:20', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5cf9ebc3-0503-4c68-95b3-f12100b73c7b'	System	08 Sep 2020 15:05:22
User entered '08 Sep 2020 10:05'	System	08 Sep 2020 15:05:22

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 09:49'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996503

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 12:19'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996504

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996505

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:07:52', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ec5a0519-e35e-440f-8527-06f79cbd5e27'	System	09 Sep 2020 00:07:59
User entered 'None (1)'	System	09 Sep 2020 00:07:59

FDA-CBER-2022-1614-0996506

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:07:53', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ec5a0519-e35e-440f-8527-06f79cbd5e27'	System	09 Sep 2020 00:07:59
User entered 'No (N)'	System	09 Sep 2020 00:07:59

FDA-CBER-2022-1614-0996507

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:07:54', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ec5a0519-e35e-440f-8527-06f79cbd5e27'	System	09 Sep 2020 00:07:59
User entered 'No (N)'	System	09 Sep 2020 00:07:59

FDA-CBER-2022-1614-0996508

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:07:56', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ec5a0519-e35e-440f-8527-06f79cbd5e27'	System	09 Sep 2020 00:07:59
User entered 'None (1)'	System	09 Sep 2020 00:07:59

FDA-CBER-2022-1614-0996509

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:07:58', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'ec5a0519-e35e-440f-8527-06f79cbd5e27'	System	09 Sep 2020 00:07:59
User entered '08 Sep 2020 19:07'	System	09 Sep 2020 00:07:59

FDA-CBER-2022-1614-0996510

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 13:14'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996511

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996512

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 2'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996513

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:18:46', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5a62f65e-66ec-45e4-a9d6-8ee349a05fcd'	System	09 Sep 2020 22:18:59
User entered 'None (1)'	System	09 Sep 2020 22:18:59

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:18:48', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5a62f65e-66ec-45e4-a9d6-8ee349a05fcd'	System	09 Sep 2020 22:18:59
User entered 'No (N)'	System	09 Sep 2020 22:18:59

FDA-CBER-2022-1614-0996515

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:18:50', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5a62f65e-66ec-45e4-a9d6-8ee349a05fcd'	System	09 Sep 2020 22:18:59
User entered 'No (N)'	System	09 Sep 2020 22:18:59

FDA-CBER-2022-1614-0996516

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:18:54', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5a62f65e-66ec-45e4-a9d6-8ee349a05fcd'	System	09 Sep 2020 22:18:59
User entered 'None (1)'	System	09 Sep 2020 22:18:59

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:18:56', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5a62f65e-66ec-45e4-a9d6-8ee349a05fcd'	System	09 Sep 2020 22:18:59
User entered '09 Sep 2020 17:18'	System	09 Sep 2020 22:18:59

FDA-CBER-2022-1614-0996518

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996519

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996520

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 3'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996521

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:06', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1a9197a4-1e4d-4013-be46-2ea37c250aae'	System	10 Sep 2020 17:18:15
User entered 'None (1)'	System	10 Sep 2020 17:18:15

FDA-CBER-2022-1614-0996522

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:08', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1a9197a4-1e4d-4013-be46-2ea37c250aae'	System	10 Sep 2020 17:18:15
User entered 'No (N)'	System	10 Sep 2020 17:18:15

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:09', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1a9197a4-1e4d-4013-be46-2ea37c250aae'	System	10 Sep 2020 17:18:15
User entered 'No (N)'	System	10 Sep 2020 17:18:15

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1a9197a4-1e4d-4013-be46-2ea37c250aae'	System	10 Sep 2020 17:18:15
User entered 'None (1)'	System	10 Sep 2020 17:18:15

FDA-CBER-2022-1614-0996525

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:13', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '1a9197a4-1e4d-4013-be46-2ea37c250aae'	System	10 Sep 2020 17:18:15
User entered '10 Sep 2020 12:18'	System	10 Sep 2020 17:18:15

FDA-CBER-2022-1614-0996526

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996527

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996528

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 4'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996529

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:05', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5970bf96-8c39-42dd-9463-3e6c4a424901'	System	12 Sep 2020 12:51:24
User entered 'None (1)'	System	12 Sep 2020 12:51:24

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:07', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5970bf96-8c39-42dd-9463-3e6c4a424901'	System	12 Sep 2020 12:51:24
User entered 'No (N)'	System	12 Sep 2020 12:51:24

FDA-CBER-2022-1614-0996531

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:10', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5970bf96-8c39-42dd-9463-3e6c4a424901'	System	12 Sep 2020 12:51:24
User entered 'No (N)'	System	12 Sep 2020 12:51:24

FDA-CBER-2022-1614-0996532

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:18', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5970bf96-8c39-42dd-9463-3e6c4a424901'	System	12 Sep 2020 12:51:24
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 12:51:24

FDA-CBER-2022-1614-0996533

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:21', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5970bf96-8c39-42dd-9463-3e6c4a424901'	System	12 Sep 2020 12:51:24
User entered '12 Sep 2020 07:51'	System	12 Sep 2020 12:51:24

FDA-CBER-2022-1614-0996534

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996535

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996536

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 5'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996537

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:20', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5269e527-a550-4c26-94a0-d60e45510aab'	System	13 Sep 2020 13:57:31
User entered 'None (1)'	System	13 Sep 2020 13:57:31

FDA-CBER-2022-1614-0996538

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:21', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5269e527-a550-4c26-94a0-d60e45510aab'	System	13 Sep 2020 13:57:31
User entered 'No (N)'	System	13 Sep 2020 13:57:31

FDA-CBER-2022-1614-0996539

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:23', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5269e527-a550-4c26-94a0-d60e45510aab'	System	13 Sep 2020 13:57:31
User entered 'No (N)'	System	13 Sep 2020 13:57:31

FDA-CBER-2022-1614-0996540

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:24', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5269e527-a550-4c26-94a0-d60e45510aab'	System	13 Sep 2020 13:57:31
User entered 'None (1)'	System	13 Sep 2020 13:57:31

FDA-CBER-2022-1614-0996541

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:27', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5269e527-a550-4c26-94a0-d60e45510aab'	System	13 Sep 2020 13:57:31
User entered '13 Sep 2020 08:57'	System	13 Sep 2020 13:57:31

FDA-CBER-2022-1614-0996542

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996543

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996544

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 6'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996545

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:18', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0be171f-8f46-4f37-a18f-f7cb1062b5a5'	System	13 Sep 2020 17:02:00
User entered 'None (1)'	System	13 Sep 2020 17:02:00

FDA-CBER-2022-1614-0996546

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:19', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0be171f-8f46-4f37-a18f-f7cb1062b5a5'	System	13 Sep 2020 17:02:00
User entered 'No (N)'	System	13 Sep 2020 17:02:00

FDA-CBER-2022-1614-0996547

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:20', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0be171f-8f46-4f37-a18f-f7cb1062b5a5'	System	13 Sep 2020 17:02:00
User entered 'No (N)'	System	13 Sep 2020 17:02:00

FDA-CBER-2022-1614-0996548

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:21', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0be171f-8f46-4f37-a18f-f7cb1062b5a5'	System	13 Sep 2020 17:02:00
User entered 'None (1)'	System	13 Sep 2020 17:02:00

FDA-CBER-2022-1614-0996549

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:23', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c0be171f-8f46-4f37-a18f-f7cb1062b5a5'	System	13 Sep 2020 17:02:00
User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:00

FDA-CBER-2022-1614-0996550

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996551

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996552

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 7'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996553

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:22', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '46291c46-7697-4cd0-9d15-3de9ddf6b98a'	System	15 Sep 2020 10:59:31
User entered 'None (1)'	System	15 Sep 2020 10:59:31

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:24', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '46291c46-7697-4cd0-9d15-3de9ddf6b98a'	System	15 Sep 2020 10:59:31
User entered 'No (N)'	System	15 Sep 2020 10:59:31

FDA-CBER-2022-1614-0996555

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:25', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '46291c46-7697-4cd0-9d15-3de9ddf6b98a'	System	15 Sep 2020 10:59:31
User entered 'No (N)'	System	15 Sep 2020 10:59:31

FDA-CBER-2022-1614-0996556

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '46291c46-7697-4cd0-9d15-3de9ddf6b98a'	System	15 Sep 2020 10:59:31
User entered 'None (1)'	System	15 Sep 2020 10:59:31

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:27', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '46291c46-7697-4cd0-9d15-3de9ddf6b98a'	System	15 Sep 2020 10:59:31
User entered '15 Sep 2020 05:59'	System	15 Sep 2020 10:59:31

FDA-CBER-2022-1614-0996558

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996559

US3452232
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996560

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996561

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:23', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58cef531-d74e-46fe-aa95-17b9c1c7bb8e'	System	08 Sep 2020 15:05:40
User entered 'None (0)'	System	08 Sep 2020 15:05:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:24', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58cef531-d74e-46fe-aa95-17b9c1c7bb8e'	System	08 Sep 2020 15:05:40
User entered 'None (0)'	System	08 Sep 2020 15:05:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58cef531-d74e-46fe-aa95-17b9c1c7bb8e'	System	08 Sep 2020 15:05:40
User entered 'None (0)'	System	08 Sep 2020 15:05:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:28', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58cef531-d74e-46fe-aa95-17b9c1c7bb8e'	System	08 Sep 2020 15:05:40
User entered 'None (0)'	System	08 Sep 2020 15:05:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:29', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58cef531-d74e-46fe-aa95-17b9c1c7bb8e'	System	08 Sep 2020 15:05:40
User entered 'None (0)'	System	08 Sep 2020 15:05:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:30', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58cef531-d74e-46fe-aa95-17b9c1c7bb8e'	System	08 Sep 2020 15:05:40
User entered 'None (0)'	System	08 Sep 2020 15:05:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:34', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58cef531-d74e-46fe-aa95-17b9c1c7bb8e'	System	08 Sep 2020 15:05:40
User entered 'No (N)'	System	08 Sep 2020 15:05:40

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T10:05:36', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '58cef531-d74e-46fe-aa95-17b9c1c7bb8e'	System	08 Sep 2020 15:05:40
User entered '08 Sep 2020 10:05'	System	08 Sep 2020 15:05:40

FDA-CBER-2022-1614-0996569

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 09:49'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996570

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 12:19'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996571

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:38:55

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:02', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'baa64f85-c4fd-4c21-bbb1-d3baa1a77ac1'	System	09 Sep 2020 00:08:13
User entered 'None (0)'	System	09 Sep 2020 00:08:13

FDA-CBER-2022-1614-0996573

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:03', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'baa64f85-c4fd-4c21-bbb1-d3baa1a77ac1'	System	09 Sep 2020 00:08:13
User entered 'None (0)'	System	09 Sep 2020 00:08:13

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:04', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'baa64f85-c4fd-4c21-bbb1-d3baa1a77ac1'	System	09 Sep 2020 00:08:13
User entered 'None (0)'	System	09 Sep 2020 00:08:13

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:05', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'baa64f85-c4fd-4c21-bbb1-d3baa1a77ac1'	System	09 Sep 2020 00:08:13
User entered 'None (0)'	System	09 Sep 2020 00:08:13

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:06', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'baa64f85-c4fd-4c21-bbb1-d3baa1a77ac1'	System	09 Sep 2020 00:08:13
User entered 'None (0)'	System	09 Sep 2020 00:08:13

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:07', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'baa64f85-c4fd-4c21-bbb1-d3baa1a77ac1'	System	09 Sep 2020 00:08:13
User entered 'None (0)'	System	09 Sep 2020 00:08:13

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:10', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'baa64f85-c4fd-4c21-bbb1-d3baa1a77ac1'	System	09 Sep 2020 00:08:13
User entered 'No (N)'	System	09 Sep 2020 00:08:13

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-08T19:08:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'baa64f85-c4fd-4c21-bbb1-d3baa1a77ac1'	System	09 Sep 2020 00:08:13
User entered '08 Sep 2020 19:08'	System	09 Sep 2020 00:08:13

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '08 Sep 2020 13:14'	System	08 Sep 2020 14:38:55

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 2'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996583

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:18:58', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b201faae-272d-41d4-a279-118e557b65e3'	System	09 Sep 2020 22:19:17
User entered 'None (0)'	System	09 Sep 2020 22:19:17

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:19:00', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b201faae-272d-41d4-a279-118e557b65e3'	System	09 Sep 2020 22:19:17
User entered 'None (0)'	System	09 Sep 2020 22:19:17

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:19:01', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b201faae-272d-41d4-a279-118e557b65e3'	System	09 Sep 2020 22:19:17
User entered 'None (0)'	System	09 Sep 2020 22:19:17

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:19:03', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b201faae-272d-41d4-a279-118e557b65e3'	System	09 Sep 2020 22:19:17
User entered 'None (0)'	System	09 Sep 2020 22:19:17

FDA-CBER-2022-1614-0996587

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:19:04', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b201faae-272d-41d4-a279-118e557b65e3'	System	09 Sep 2020 22:19:17
User entered 'None (0)'	System	09 Sep 2020 22:19:17

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:19:06', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b201faae-272d-41d4-a279-118e557b65e3'	System	09 Sep 2020 22:19:17
User entered 'None (0)'	System	09 Sep 2020 22:19:17

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:19:12', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b201faae-272d-41d4-a279-118e557b65e3'	System	09 Sep 2020 22:19:17
User entered 'No (N)'	System	09 Sep 2020 22:19:17

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-09T17:19:15', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'b201faae-272d-41d4-a279-118e557b65e3'	System	09 Sep 2020 22:19:17
User entered '09 Sep 2020 17:19'	System	09 Sep 2020 22:19:17

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996593

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 3'	System	08 Sep 2020 14:38:55

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fa32d05f-aa38-45ed-a0f9-1adfd3420d8d'	System	10 Sep 2020 17:18:40
User entered 'None (0)'	System	10 Sep 2020 17:18:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:18', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fa32d05f-aa38-45ed-a0f9-1adfd3420d8d'	System	10 Sep 2020 17:18:40
User entered 'None (0)'	System	10 Sep 2020 17:18:40

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:19', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fa32d05f-aa38-45ed-a0f9-1adfd3420d8d'	System	10 Sep 2020 17:18:40
User entered 'None (0)'	System	10 Sep 2020 17:18:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:21', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fa32d05f-aa38-45ed-a0f9-1adfd3420d8d'	System	10 Sep 2020 17:18:40
User entered 'None (0)'	System	10 Sep 2020 17:18:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:22', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fa32d05f-aa38-45ed-a0f9-1adfd3420d8d'	System	10 Sep 2020 17:18:40
User entered 'None (0)'	System	10 Sep 2020 17:18:40

FDA-CBER-2022-1614-0996599

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:23', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fa32d05f-aa38-45ed-a0f9-1adfd3420d8d'	System	10 Sep 2020 17:18:40
User entered 'None (0)'	System	10 Sep 2020 17:18:40

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:37', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fa32d05f-aa38-45ed-a0f9-1adfd3420d8d'	System	10 Sep 2020 17:18:40
User entered 'No (N)'	System	10 Sep 2020 17:18:40

FDA-CBER-2022-1614-0996601

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-10T12:18:38', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'fa32d05f-aa38-45ed-a0f9-1adfd3420d8d'	System	10 Sep 2020 17:18:40
User entered '10 Sep 2020 12:18'	System	10 Sep 2020 17:18:40

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US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996603

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996604

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 4'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996605

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:27', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c83515db-3d96-420f-b216-62b833b5494c'	System	12 Sep 2020 12:51:55
User entered 'None (0)'	System	12 Sep 2020 12:51:55

FDA-CBER-2022-1614-0996606

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:35', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c83515db-3d96-420f-b216-62b833b5494c'	System	12 Sep 2020 12:51:55
User entered 'None (0)'	System	12 Sep 2020 12:51:55

FDA-CBER-2022-1614-0996607

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:38', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c83515db-3d96-420f-b216-62b833b5494c'	System	12 Sep 2020 12:51:55
User entered 'None (0)'	System	12 Sep 2020 12:51:55

FDA-CBER-2022-1614-0996608

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:41', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c83515db-3d96-420f-b216-62b833b5494c'	System	12 Sep 2020 12:51:55
User entered 'None (0)'	System	12 Sep 2020 12:51:55

FDA-CBER-2022-1614-0996609

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:43', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c83515db-3d96-420f-b216-62b833b5494c'	System	12 Sep 2020 12:51:55
User entered 'None (0)'	System	12 Sep 2020 12:51:55

FDA-CBER-2022-1614-0996610

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:45', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c83515db-3d96-420f-b216-62b833b5494c'	System	12 Sep 2020 12:51:55
User entered 'None (0)'	System	12 Sep 2020 12:51:55

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:48', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c83515db-3d96-420f-b216-62b833b5494c'	System	12 Sep 2020 12:51:55
User entered 'No (N)'	System	12 Sep 2020 12:51:55

FDA-CBER-2022-1614-0996612

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-12T07:51:52', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c83515db-3d96-420f-b216-62b833b5494c'	System	12 Sep 2020 12:51:55
User entered '12 Sep 2020 07:51'	System	12 Sep 2020 12:51:55

FDA-CBER-2022-1614-0996613

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996614

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996615

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 5'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996616

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:30', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'af21baa6-2d57-4656-9163-4b568310642b'	System	13 Sep 2020 13:57:57
User entered 'None (0)'	System	13 Sep 2020 13:57:57

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'af21baa6-2d57-4656-9163-4b568310642b'	System	13 Sep 2020 13:57:57
User entered 'None (0)'	System	13 Sep 2020 13:57:57

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:48', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'af21baa6-2d57-4656-9163-4b568310642b'	System	13 Sep 2020 13:57:57
User entered 'None (0)'	System	13 Sep 2020 13:57:57

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:49', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'af21baa6-2d57-4656-9163-4b568310642b'	System	13 Sep 2020 13:57:57
User entered 'None (0)'	System	13 Sep 2020 13:57:57

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:50', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'af21baa6-2d57-4656-9163-4b568310642b'	System	13 Sep 2020 13:57:57
User entered 'None (0)'	System	13 Sep 2020 13:57:57

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:51', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'af21baa6-2d57-4656-9163-4b568310642b'	System	13 Sep 2020 13:57:57
User entered 'None (0)'	System	13 Sep 2020 13:57:57

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:54', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'af21baa6-2d57-4656-9163-4b568310642b'	System	13 Sep 2020 13:57:57
User entered 'No (N)'	System	13 Sep 2020 13:57:57

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T08:57:56', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'af21baa6-2d57-4656-9163-4b568310642b'	System	13 Sep 2020 13:57:57
User entered '13 Sep 2020 08:57'	System	13 Sep 2020 13:57:57

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996625

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996626

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 6'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996627

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:00:59', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '6e20c184-ffa1-4c52-8387-165f4aa4ae6d'	System	13 Sep 2020 17:01:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Sep 2020 17:01:49

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:09', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '6e20c184-ffa1-4c52-8387-165f4aa4ae6d'	System	13 Sep 2020 17:01:49
User entered 'None (0)'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996629

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:07', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '6e20c184-ffa1-4c52-8387-165f4aa4ae6d'	System	13 Sep 2020 17:01:49
User entered 'None (0)'	System	13 Sep 2020 17:01:49

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:06', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '6e20c184-ffa1-4c52-8387-165f4aa4ae6d'	System	13 Sep 2020 17:01:49
User entered 'None (0)'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996631

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:05', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '6e20c184-ffa1-4c52-8387-165f4aa4ae6d'	System	13 Sep 2020 17:01:49
User entered 'None (0)'	System	13 Sep 2020 17:01:49

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '6e20c184-ffa1-4c52-8387-165f4aa4ae6d'	System	13 Sep 2020 17:01:49
User entered 'None (0)'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996633

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:12', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '6e20c184-ffa1-4c52-8387-165f4aa4ae6d'	System	13 Sep 2020 17:01:49
User entered 'No (N)'	System	13 Sep 2020 17:01:49

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-13T12:01:14', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '6e20c184-ffa1-4c52-8387-165f4aa4ae6d'	System	13 Sep 2020 17:01:49
User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996635

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996636

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996637

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	08 Sep 2020 14:38:55
User entered 'Day 7'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996638

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:32', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '59168b30-cb36-4cfb-a007-13d37e44eed9'	System	15 Sep 2020 10:59:44
User entered 'No interference with activity (1)'	System	15 Sep 2020 10:59:44

FDA-CBER-2022-1614-0996639

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:33', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '59168b30-cb36-4cfb-a007-13d37e44eed9'	System	15 Sep 2020 10:59:44
User entered 'None (0)'	System	15 Sep 2020 10:59:44

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:34', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '59168b30-cb36-4cfb-a007-13d37e44eed9'	System	15 Sep 2020 10:59:44
User entered 'None (0)'	System	15 Sep 2020 10:59:44

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:35', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '59168b30-cb36-4cfb-a007-13d37e44eed9'	System	15 Sep 2020 10:59:44
User entered 'None (0)'	System	15 Sep 2020 10:59:44

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:36', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '59168b30-cb36-4cfb-a007-13d37e44eed9'	System	15 Sep 2020 10:59:44
User entered 'None (0)'	System	15 Sep 2020 10:59:44

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:37', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '59168b30-cb36-4cfb-a007-13d37e44eed9'	System	15 Sep 2020 10:59:44
User entered 'None (0)'	System	15 Sep 2020 10:59:44

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:39', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '59168b30-cb36-4cfb-a007-13d37e44eed9'	System	15 Sep 2020 10:59:44
User entered 'No (N)'	System	15 Sep 2020 10:59:44

FDA-CBER-2022-1614-0996645

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T05:59:41', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '59168b30-cb36-4cfb-a007-13d37e44eed9'	System	15 Sep 2020 10:59:44
User entered '15 Sep 2020 05:59'	System	15 Sep 2020 10:59:44

FDA-CBER-2022-1614-0996646

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996647

US3452232
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:38:55

FDA-CBER-2022-1614-0996648

US3452232
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	13 Sep 2020 17:01:49
User entered 'Day 8'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996649

US3452232
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 22:46:20

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T15:21:39', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9913ccb9-4b39-4a2f-8499-39d3c568c355'	System	15 Sep 2020 20:21:45
User entered 'None (0)'	System	15 Sep 2020 20:21:45

FDA-CBER-2022-1614-0996650

US3452232
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 22:46:20
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T15:21:41', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9913ccb9-4b39-4a2f-8499-39d3c568c355'	System	15 Sep 2020 20:21:45
User entered '15 Sep 2020 15:21'	System	15 Sep 2020 20:21:45

US3452232
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996652

US3452232
Folder: Diary Dose 2 (1)
Form: Headache_Day(8)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996653

US3452232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	13 Sep 2020 17:01:49
User entered 'Day 8'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996654

US3452232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 22:46:20
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 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T15:21:45', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8da5d02d-b51a-4728-be48-ca57af671213'	System	15 Sep 2020 20:21:51
User entered 'No (N)'	System	15 Sep 2020 20:21:51

US3452232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 22:46:20
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-09-15T15:21:47', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '8da5d02d-b51a-4728-be48-ca57af671213'	System	15 Sep 2020 20:21:51
User entered '15 Sep 2020 15:21'	System	15 Sep 2020 20:21:51

US3452232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 22:46:20
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996657

US3452232
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 11 Aug 2021 22:46:20
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 17:01:49

FDA-CBER-2022-1614-0996658

US3452232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Sep 2020 13:25:18

US3452232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered '15 Sep 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Sep 2020 13:25:18

FDA-CBER-2022-1614-0996660

US3452232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Contact Made (CONTACT MADE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Sep 2020 13:25:18

US3452232
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Sep 2020 13:25:18

FDA-CBER-2022-1614-0996662

US3452232
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Sep 2020 13:35:03

US3452232
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	22 Sep 2020 13:35:03

FDA-CBER-2022-1614-0996664

US3452232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Sep 2020 13:35:14

US3452232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered '22 Sep 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Sep 2020 13:35:14

FDA-CBER-2022-1614-0996666

US3452232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Contact Made (CONTACT MADE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Sep 2020 13:35:14

US3452232
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Sep 2020 13:35:14

FDA-CBER-2022-1614-0996668

US3452232
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Sep 2020 14:15:37

FDA-CBER-2022-1614-0996669

US3452232
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	29 Sep 2020 14:15:37

FDA-CBER-2022-1614-0996670

US3452232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Sep 2020 14:15:50

US3452232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered '29 Sep 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Sep 2020 14:15:50

FDA-CBER-2022-1614-0996672

US3452232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Contact Made (CONTACT MADE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Sep 2020 14:15:50

US3452232
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Sep 2020 14:15:50

FDA-CBER-2022-1614-0996674

US3452232
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:02
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:30

FDA-CBER-2022-1614-0996675

US3452232
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	07 Oct 2020 21:03:30

FDA-CBER-2022-1614-0996676

US3452232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:45

FDA-CBER-2022-1614-0996677

US3452232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '07 Oct 2020'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:45

FDA-CBER-2022-1614-0996678

US3452232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
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 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:45

FDA-CBER-2022-1614-0996679

US3452232
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered 'VISIT3'	System	07 Oct 2020 21:03:45

FDA-CBER-2022-1614-0996680

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996683

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996684

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996685

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996688

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996689

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996690

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996691

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996692

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996693

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996694

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	07 Oct 2020 21:03:51

FDA-CBER-2022-1614-0996695

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55

FDA-CBER-2022-1614-0996696

US3452232
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55

FDA-CBER-2022-1614-0996697

US3452232
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:59

US3452232
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '07 Oct 2020'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:03:59

FDA-CBER-2022-1614-0996699

US3452232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:04:09

FDA-CBER-2022-1614-0996700

US3452232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '07 Oct 2020'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:04:09

FDA-CBER-2022-1614-0996701

US3452232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered '09:25'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 21:04:09

FDA-CBER-2022-1614-0996702

US3452232
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 11 Aug 2021 22:46:20
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '07 Oct 2020 09:25'	System	07 Oct 2020 21:04:09

FDA-CBER-2022-1614-0996703

US3452232
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	17 Feb 2021 18:08:06
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	28 Oct 2020 16:02:10

US3452232
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	28 Oct 2020 16:02:10

FDA-CBER-2022-1614-0996705

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 64'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996706

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-05T08:12:32', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '39515ac1-dad7-47e6-ac90-8a346131d518'	System	05 Oct 2020 13:12:41
User entered 'No (N)'	System	05 Oct 2020 13:12:41

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-05T08:12:36', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '39515ac1-dad7-47e6-ac90-8a346131d518'	System	05 Oct 2020 13:12:41
User entered 'No (N)'	System	05 Oct 2020 13:12:41

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-05T08:12:39', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '39515ac1-dad7-47e6-ac90-8a346131d518'	System	05 Oct 2020 13:12:41
User entered '05 Oct 2020 08:12:39'	System	05 Oct 2020 13:12:41

FDA-CBER-2022-1614-0996709

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996710

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996711

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 71'	System	05 Aug 2020 15:33:58

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-12T07:58:43', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '0e66c833-127c-4a3f-9c4f-4ac6c138f66e'	System	12 Oct 2020 12:58:55
User entered 'No (N)'	System	12 Oct 2020 12:58:55

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-12T07:58:49', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '0e66c833-127c-4a3f-9c4f-4ac6c138f66e'	System	12 Oct 2020 12:58:55
User entered 'No (N)'	System	12 Oct 2020 12:58:55

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-12T07:58:52', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '0e66c833-127c-4a3f-9c4f-4ac6c138f66e'	System	12 Oct 2020 12:58:55
User entered '12 Oct 2020 07:58:52'	System	12 Oct 2020 12:58:55

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996716

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996717

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 78'	System	05 Aug 2020 15:33:58

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-19T08:26:43', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '88e0bb90-5270-4392-b05f-2c5dd15c005d'	System	19 Oct 2020 13:26:58
User entered 'No (N)'	System	19 Oct 2020 13:26:58

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-19T08:26:53', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '88e0bb90-5270-4392-b05f-2c5dd15c005d'	System	19 Oct 2020 13:26:58
User entered 'No (N)'	System	19 Oct 2020 13:26:58

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-10-19T08:26:55', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '88e0bb90-5270-4392-b05f-2c5dd15c005d'	System	19 Oct 2020 13:26:58
User entered '19 Oct 2020 08:26:55'	System	19 Oct 2020 13:26:58

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996722

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996723

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 92'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996724

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-03T12:34:30', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '0211ebb5-cd21-4822-869a-4a062c1d6d6d'	System	03 Nov 2020 18:34:34
User entered 'No (N)'	System	03 Nov 2020 18:34:34

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-03T12:34:31', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '0211ebb5-cd21-4822-869a-4a062c1d6d6d'	System	03 Nov 2020 18:34:34
User entered 'No (N)'	System	03 Nov 2020 18:34:34

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-03T12:34:33', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '0211ebb5-cd21-4822-869a-4a062c1d6d6d'	System	03 Nov 2020 18:34:34
User entered '03 Nov 2020 12:34:33'	System	03 Nov 2020 18:34:34

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996728

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996729

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 99'	System	05 Aug 2020 15:33:58

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-09T08:30:43', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9b28a735-ea99-4787-a488-65c4a2084eec'	System	09 Nov 2020 14:30:56
User entered 'No (N)'	System	09 Nov 2020 14:30:56

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-09T08:30:48', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9b28a735-ea99-4787-a488-65c4a2084eec'	System	09 Nov 2020 14:30:56
User entered 'No (N)'	System	09 Nov 2020 14:30:56

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-09T08:30:50', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '9b28a735-ea99-4787-a488-65c4a2084eec'	System	09 Nov 2020 14:30:56
User entered '09 Nov 2020 08:30:50'	System	09 Nov 2020 14:30:56

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996734

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996735

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered 'Day 106'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996736

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-16T07:47:56', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '4de760a6-c5fb-405c-8fc4-ab0d7779b699'	System	16 Nov 2020 13:48:06
User entered 'No (N)'	System	16 Nov 2020 13:48:06

US3452232

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-16T07:48:00', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '4de760a6-c5fb-405c-8fc4-ab0d7779b699'	System	16 Nov 2020 13:48:06
User entered 'No (N)'	System	16 Nov 2020 13:48:06

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-16T07:48:03', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '4de760a6-c5fb-405c-8fc4-ab0d7779b699'	System	16 Nov 2020 13:48:06
User entered '16 Nov 2020 07:48:03'	System	16 Nov 2020 13:48:06

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996740

US3452232
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:53:53
Data entry locked.	System	05 Aug 2020 15:33:58
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 15:33:58

FDA-CBER-2022-1614-0996741

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996742

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-23T08:23:42', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '70a19d5f-6a71-4770-9247-a41b11b7aef3'	System	23 Nov 2020 14:23:56
User entered 'No (N)'	System	23 Nov 2020 14:23:56

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-23T08:23:50', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '70a19d5f-6a71-4770-9247-a41b11b7aef3'	System	23 Nov 2020 14:23:56
User entered 'No (N)'	System	23 Nov 2020 14:23:56

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-23T08:23:53', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '70a19d5f-6a71-4770-9247-a41b11b7aef3'	System	23 Nov 2020 14:23:56
User entered '23 Nov 2020 08:23:53'	System	23 Nov 2020 14:23:56

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996746

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996747

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996748

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-27T07:50:51', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '88d5e803-b1d2-4180-83ef-2077d5d4aded'	System	27 Nov 2020 13:51:01
User entered 'No (N)'	System	27 Nov 2020 13:51:01

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-27T07:50:56', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '88d5e803-b1d2-4180-83ef-2077d5d4aded'	System	27 Nov 2020 13:51:01
User entered 'No (N)'	System	27 Nov 2020 13:51:01

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-11-27T07:50:58', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '88d5e803-b1d2-4180-83ef-2077d5d4aded'	System	27 Nov 2020 13:51:01
User entered '27 Nov 2020 07:50:58'	System	27 Nov 2020 13:51:01

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996752

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996753

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996754

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-06T12:00:55', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '54c19d39-4e10-472c-8fcb-e1f8364b9d6e'	System	06 Dec 2020 18:01:06
User entered 'No (N)'	System	06 Dec 2020 18:01:06

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-06T12:01:01', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '54c19d39-4e10-472c-8fcb-e1f8364b9d6e'	System	06 Dec 2020 18:01:06
User entered 'No (N)'	System	06 Dec 2020 18:01:06

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-06T12:01:03', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '54c19d39-4e10-472c-8fcb-e1f8364b9d6e'	System	06 Dec 2020 18:01:06
User entered '06 Dec 2020 12:01:03'	System	06 Dec 2020 18:01:06

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996758

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996759

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:16:02

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US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:25:55', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered 'Yes (Y)'	System	12 Dec 2020 00:26:45

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:25:57', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered 'Yes (Y)'	System	12 Dec 2020 00:26:45

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Please 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:25:59', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 00:26:45

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:02', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered 'Yes (Y)'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '1'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

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US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '1'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '1'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '1'	System	12 Dec 2020 00:26:45

FDA-CBER-2022-1614-0996777

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

FDA-CBER-2022-1614-0996780

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '0'	System	12 Dec 2020 00:26:45

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Please 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:19', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 00:26:45

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered 'No (N)'	System	12 Dec 2020 00:26:45

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-11T18:26:32', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '52dafdc6-8988-47f9-9ac5-c5202044ba38'	System	12 Dec 2020 00:26:45
User entered '11 Dec 2020 18:26:32'	System	12 Dec 2020 00:26:45

FDA-CBER-2022-1614-0996784

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996785

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996786

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996787

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-18T05:06:07', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '30adeae8-25ff-4cbb-b485-9cd214f7d1c3'	System	18 Dec 2020 11:06:26
User entered 'No (N)'	System	18 Dec 2020 11:06:26

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-18T05:06:21', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '30adeae8-25ff-4cbb-b485-9cd214f7d1c3'	System	18 Dec 2020 11:06:26
User entered 'No (N)'	System	18 Dec 2020 11:06:26

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-18T05:06:23', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '30adeae8-25ff-4cbb-b485-9cd214f7d1c3'	System	18 Dec 2020 11:06:26
User entered '18 Dec 2020 05:06:23'	System	18 Dec 2020 11:06:26

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996791

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996792

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996793

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-25T02:52:44', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'aad6c87e-1962-4f3a-8654-8eaa329b1716'	System	25 Dec 2020 08:52:55
User entered 'No (N)'	System	25 Dec 2020 08:52:55

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-25T02:52:51', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'aad6c87e-1962-4f3a-8654-8eaa329b1716'	System	25 Dec 2020 08:52:55
User entered 'No (N)'	System	25 Dec 2020 08:52:55

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2020-12-25T02:52:54', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'aad6c87e-1962-4f3a-8654-8eaa329b1716'	System	25 Dec 2020 08:52:55
User entered '25 Dec 2020 02:52:54'	System	25 Dec 2020 08:52:55

FDA-CBER-2022-1614-0996796

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996797

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996798

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996799

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-03T12:01:09', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'a8caf3a9-b666-4986-8215-d66e17923de9'	System	03 Jan 2021 18:01:18
User entered 'No (N)'	System	03 Jan 2021 18:01:18

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-03T12:01:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'a8caf3a9-b666-4986-8215-d66e17923de9'	System	03 Jan 2021 18:01:18
User entered 'No (N)'	System	03 Jan 2021 18:01:18

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-03T12:01:13', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'a8caf3a9-b666-4986-8215-d66e17923de9'	System	03 Jan 2021 18:01:18
User entered '03 Jan 2021 12:01:13'	System	03 Jan 2021 18:01:18

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996803

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996804

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996805

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-08T10:10:03', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '586eaa90-be86-43e8-ae77-75fd526d0d0f'	System	08 Jan 2021 16:10:12
User entered 'No (N)'	System	08 Jan 2021 16:10:12

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-08T10:10:06', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '586eaa90-be86-43e8-ae77-75fd526d0d0f'	System	08 Jan 2021 16:10:12
User entered 'No (N)'	System	08 Jan 2021 16:10:12

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-08T10:10:08', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '586eaa90-be86-43e8-ae77-75fd526d0d0f'	System	08 Jan 2021 16:10:12
User entered '08 Jan 2021 10:10:08'	System	08 Jan 2021 16:10:12

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996809

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996810

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996811

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-15T07:24:21', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c7187b3d-5907-4afc-96e9-e5963dbcc633'	System	15 Jan 2021 13:24:38
User entered 'No (N)'	System	15 Jan 2021 13:24:38

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-15T07:24:26', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c7187b3d-5907-4afc-96e9-e5963dbcc633'	System	15 Jan 2021 13:24:38
User entered 'No (N)'	System	15 Jan 2021 13:24:38

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-15T07:24:35', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: 'c7187b3d-5907-4afc-96e9-e5963dbcc633'	System	15 Jan 2021 13:24:38
User entered '15 Jan 2021 07:24:35'	System	15 Jan 2021 13:24:38

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996815

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996816

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996817

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-22T09:26:51', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '217fda15-db37-417c-ab1f-0414be837a4f'	System	22 Jan 2021 15:26:58
User entered 'No (N)'	System	22 Jan 2021 15:26:58

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-22T09:26:53', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '217fda15-db37-417c-ab1f-0414be837a4f'	System	22 Jan 2021 15:26:58
User entered 'No (N)'	System	22 Jan 2021 15:26:58

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-22T09:26:56', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '217fda15-db37-417c-ab1f-0414be837a4f'	System	22 Jan 2021 15:26:58
User entered '22 Jan 2021 09:26:56'	System	22 Jan 2021 15:26:58

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996821

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996822

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996823

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-31T13:32:42', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '764b7093-ef16-441c-9970-cecd6b73474c'	System	31 Jan 2021 19:32:54
User entered 'No (N)'	System	31 Jan 2021 19:32:54

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-31T13:32:45', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '764b7093-ef16-441c-9970-cecd6b73474c'	System	31 Jan 2021 19:32:54
User entered 'No (N)'	System	31 Jan 2021 19:32:54

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-01-31T13:32:48', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '764b7093-ef16-441c-9970-cecd6b73474c'	System	31 Jan 2021 19:32:54
User entered '31 Jan 2021 13:32:48'	System	31 Jan 2021 19:32:54

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996827

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996828

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996829

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-06T09:02:12', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '4ff227cf-e05c-4e18-bca0-4ac069e5b07d'	System	06 Feb 2021 15:02:21
User entered 'No (N)'	System	06 Feb 2021 15:02:21

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-06T09:02:14', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '4ff227cf-e05c-4e18-bca0-4ac069e5b07d'	System	06 Feb 2021 15:02:21
User entered 'No (N)'	System	06 Feb 2021 15:02:21

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-06T09:02:16', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '4ff227cf-e05c-4e18-bca0-4ac069e5b07d'	System	06 Feb 2021 15:02:21
User entered '06 Feb 2021 09:02:16'	System	06 Feb 2021 15:02:21

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996833

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996834

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996835

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-12T07:41:09', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5fde1848-403f-4f89-90ad-cdbf1e03f8c0'	System	12 Feb 2021 13:41:18
User entered 'No (N)'	System	12 Feb 2021 13:41:18

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-12T07:41:11', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5fde1848-403f-4f89-90ad-cdbf1e03f8c0'	System	12 Feb 2021 13:41:18
User entered 'No (N)'	System	12 Feb 2021 13:41:18

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-12T07:41:14', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '5fde1848-403f-4f89-90ad-cdbf1e03f8c0'	System	12 Feb 2021 13:41:18
User entered '12 Feb 2021 07:41:14'	System	12 Feb 2021 13:41:18

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996839

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996840

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996841

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-19T07:34:13', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '04197a80-16d2-44eb-8e51-60af5de009c5'	System	19 Feb 2021 13:34:20
User entered 'No (N)'	System	19 Feb 2021 13:34:20

US3452232

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:46:20

Have you been exposed to someone with 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)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-19T07:34:15', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '04197a80-16d2-44eb-8e51-60af5de009c5'	System	19 Feb 2021 13:34:20
User entered 'No (N)'	System	19 Feb 2021 13:34:20

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D216CAB7-6CBE-4EF0-BCF2-761557B20798)', Time: '2021-02-19T07:34:17', User OID: 'PatientReportedOutcome (US3452232)', ODM File OID: '04197a80-16d2-44eb-8e51-60af5de009c5'	System	19 Feb 2021 13:34:20
User entered '19 Feb 2021 07:34:17'	System	19 Feb 2021 13:34:20

FDA-CBER-2022-1614-0996844

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996845

US3452232
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 11 Aug 2021 22:46:20
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:16:02
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:16:02

FDA-CBER-2022-1614-0996846

US3452232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	28 Oct 2020 16:02:24

FDA-CBER-2022-1614-0996847

US3452232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	26 Nov 2020 08:47:45
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'This is day 84 from baseline. ' (Site from System).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	28 Oct 2020 23:03:43
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Oct 2020 16:02:24
User entered '28 Oct 2020'	Chalimar Rojo (b) (4) (b) (4)	28 Oct 2020 16:02:24

FDA-CBER-2022-1614-0996848

US3452232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4) (b) (4)	28 Oct 2020 16:02:24

FDA-CBER-2022-1614-0996849

US3452232
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	28 Oct 2020 16:02:24

FDA-CBER-2022-1614-0996850

US3452232
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	28 Oct 2020 16:02:34

FDA-CBER-2022-1614-0996851

US3452232
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered '1'	System	28 Oct 2020 16:02:34

FDA-CBER-2022-1614-0996852

US3452232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	07 Dec 2020 15:47:24

US3452232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered '7 Dec 2020'	Chalimar Rojo (b) (4) (b) (4)	07 Dec 2020 15:47:24

US3452232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4) (b) (4)	07 Dec 2020 15:47:24

US3452232
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	07 Dec 2020 15:47:24

FDA-CBER-2022-1614-0996856

US3452232
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	06 Jan 2021 00:40:35

FDA-CBER-2022-1614-0996857

US3452232
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	06 Jan 2021 00:40:35

US3452232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	04 Feb 2021 23:15:40

FDA-CBER-2022-1614-0996859

US3452232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered '06 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	04 Feb 2021 23:15:40

US3452232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Contact Made (CONTACT MADE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	04 Feb 2021 23:15:40

FDA-CBER-2022-1614-0996861

US3452232
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	04 Feb 2021 23:15:40

FDA-CBER-2022-1614-0996862

US3452232
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	05 Feb 2021 18:31:41

FDA-CBER-2022-1614-0996863

US3452232
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	05 Feb 2021 18:31:41

FDA-CBER-2022-1614-0996864

US3452232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Yes (Y)'	Chalimar Rojo (b) (4) (b) (4)	05 Feb 2021 18:31:54

FDA-CBER-2022-1614-0996865

US3452232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered '5 Feb 2021'	Chalimar Rojo (b) (4) (b) (4)	05 Feb 2021 18:31:54

US3452232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4) (b) (4)	05 Feb 2021 18:31:54

US3452232
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 11 Aug 2021 22:46:20
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Chalimar Rojo (b) (4) (b) (4)	05 Feb 2021 18:31:54

FDA-CBER-2022-1614-0996868

US3452232
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:22:33
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Feb 2021 16:07:17

US3452232
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 11 Aug 2021 22:46:20
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:55
User entered empty.	System	22 Feb 2021 22:22:33
User entered '1'	System	08 Feb 2021 16:07:17

FDA-CBER-2022-1614-0996870

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:20
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:15
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:15:08
User closed query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (11DEC2020). Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:45:48
Query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (11DEC2020). Please review and reconcile' answered with 'Yes. I contacted patient 11DEC2020, and started recording the symptoms at the start date. please clarify. ' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 20:01:00
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:52:53
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:47:44
User closed query 'Per ETRTR: Please add Severity Assessment page as expected, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Jan 2021 17:54:04
User opened query 'Per CDM: It appears initial start date of symptoms and Contact Date are the same (11DEC2020). Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:40:42
Query 'Per ETRTR: Please add Severity Assessment page as expected, thanks.' answered with 'updated' (Site from CRA).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:58
User opened query 'Per ETRTR: Please add Severity Assessment page as expected, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 23:02:19
User entered '11 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:15:54

FDA-CBER-2022-1614-0996871

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:20
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:15
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:15:08
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:52:56
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:47:44
User entered '07:50'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:15:54

FDA-CBER-2022-1614-0996872

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:20
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:15
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '11 Dec 2020 07:50'	System	15 Dec 2020 18:15:54

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:20
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:15
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:15:08
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:00
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:47:44
User closed query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Jan 2021 17:54:19
Query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' answered with 'updated' (Site from CRA).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:09:19
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:09:14
User opened query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 23:00:47
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:15:54

FDA-CBER-2022-1614-0996874

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID-19 Contact
Generated On: 11 Aug 2021 22:46:20
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:15
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:15:08
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:03
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:47:44
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:15:54

FDA-CBER-2022-1614-0996875

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 1 (Day 1)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '11 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996877

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996878

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered missing code ND - Not Done.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996879

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	15 Dec 2020 18:17:29

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered missing code ND - Not Done.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996881

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996882

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996883

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996884

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996885

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996886

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996887

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996888

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996889

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996891

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996892

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996894

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996895

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (1)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:17:29

FDA-CBER-2022-1614-0996897

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 2 (Day 2)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '12 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered missing code ND - Not Done.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

FDA-CBER-2022-1614-0996901

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	15 Dec 2020 18:18:48

FDA-CBER-2022-1614-0996902

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered missing code ND - Not Done.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

FDA-CBER-2022-1614-0996903

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

FDA-CBER-2022-1614-0996906

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

FDA-CBER-2022-1614-0996908

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

FDA-CBER-2022-1614-0996915

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

FDA-CBER-2022-1614-0996916

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (2)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:18:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 3 (Day 3)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '13 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

FDA-CBER-2022-1614-0996922

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered missing code ND - Not Done.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

FDA-CBER-2022-1614-0996923

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	15 Dec 2020 18:19:47

FDA-CBER-2022-1614-0996924

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered missing code ND - Not Done.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

FDA-CBER-2022-1614-0996925

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

FDA-CBER-2022-1614-0996926

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

FDA-CBER-2022-1614-0996929

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

FDA-CBER-2022-1614-0996939

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

FDA-CBER-2022-1614-0996940

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (3)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:19:47

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 4 (Day 4)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '14 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996944

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered missing code ND - Not Done.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996945

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	15 Dec 2020 18:21:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered missing code ND - Not Done.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996948

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996954

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996955

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996956

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996957

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996958

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996959

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996960

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996961

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996962

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (4)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:21:10

FDA-CBER-2022-1614-0996963

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 5 (Day 5)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '15 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

FDA-CBER-2022-1614-0996966

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '100'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	15 Dec 2020 18:22:10

FDA-CBER-2022-1614-0996968

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.4' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

FDA-CBER-2022-1614-0996969

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

FDA-CBER-2022-1614-0996971

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

FDA-CBER-2022-1614-0996972

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

FDA-CBER-2022-1614-0996973

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

FDA-CBER-2022-1614-0996983

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (5)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 18:22:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 6 (Day 6)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '16 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996987

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996988

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '96'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996989

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996990

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.8' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996991

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996992

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996994

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996995

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996996

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996997

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0996999

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0997000

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

FDA-CBER-2022-1614-0997003

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (6)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:30:40

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 7 (Day 7)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '17 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

FDA-CBER-2022-1614-0997011

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '97.9' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

FDA-CBER-2022-1614-0997013

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

FDA-CBER-2022-1614-0997016

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

FDA-CBER-2022-1614-0997017

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

FDA-CBER-2022-1614-0997018

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

FDA-CBER-2022-1614-0997019

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

FDA-CBER-2022-1614-0997023

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (7)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:31:48

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 8 (Day 8)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '18 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.5' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (8)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	19 Dec 2020 00:32:57

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 9 (Day 9)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '19 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '97'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	23 Dec 2020 20:39:05

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.0' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (9)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:39:05

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 10 (Day 10)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '20 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '97'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	23 Dec 2020 20:40:53

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '99.8' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Not Done (Not Done)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

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Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

FDA-CBER-2022-1614-0997086

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

FDA-CBER-2022-1614-0997089

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

FDA-CBER-2022-1614-0997090

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

FDA-CBER-2022-1614-0997091

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

FDA-CBER-2022-1614-0997092

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

FDA-CBER-2022-1614-0997093

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

FDA-CBER-2022-1614-0997094

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (10)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:40:53

FDA-CBER-2022-1614-0997095

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 11 (Day 11)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '21 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '94'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

FDA-CBER-2022-1614-0997099

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '99.9' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (11)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:42:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 12 (Day 12)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '22 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

FDA-CBER-2022-1614-0997120

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '100.5' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

FDA-CBER-2022-1614-0997123

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

FDA-CBER-2022-1614-0997125

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

FDA-CBER-2022-1614-0997126

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

FDA-CBER-2022-1614-0997127

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

FDA-CBER-2022-1614-0997129

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

FDA-CBER-2022-1614-0997130

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

FDA-CBER-2022-1614-0997133

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (12)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:43:39

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 13 (Day 13)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '23 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '88'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997143

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997144

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '101.6' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997145

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997146

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997147

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997148

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997149

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997150

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997153

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997154

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997155

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997156

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997157

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997158

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

FDA-CBER-2022-1614-0997159

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (13)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:40:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 14 (Day 14)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '24 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997164

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '88'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	29 Dec 2020 14:41:17

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '101.7' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997169

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997170

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997171

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997172

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997173

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997174

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997175

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997176

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997177

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997178

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997179

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997180

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997181

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997182

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (14)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:41:17

FDA-CBER-2022-1614-0997183

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 15 (Day 15)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '25 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '94'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997187

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997188

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '101.0' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997189

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997190

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997191

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997192

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997194

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997195

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997196

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997197

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997198

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997199

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

FDA-CBER-2022-1614-0997201

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (15)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:42:25

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 16 (Day 16)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '26 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '86'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997209

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997210

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.9' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997211

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997212

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997214

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997215

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997219

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997220

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997221

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997222

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997223

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997224

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997225

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997226

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (16)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:43:38

FDA-CBER-2022-1614-0997227

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 17 (Day 17)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '27 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '88'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997231

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997232

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.7' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997233

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997235

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997236

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997237

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997238

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997239

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997240

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997241

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997242

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997243

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997244

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997245

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997246

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997247

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

FDA-CBER-2022-1614-0997248

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (17)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:45:02

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 18 (Day 18)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '28 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997252

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '93'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997253

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	29 Dec 2020 14:46:26

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.9' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997255

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997256

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997257

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997258

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997259

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997260

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997261

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997262

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Moderate (Moderate)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997263

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997264

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997265

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997266

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997267

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997268

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997269

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997270

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (18)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:46:26

FDA-CBER-2022-1614-0997271

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 19 (Day 19)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

FDA-CBER-2022-1614-0997272

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '29 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	05 Jan 2021 13:42:06

FDA-CBER-2022-1614-0997276

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.9' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

FDA-CBER-2022-1614-0997278

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

FDA-CBER-2022-1614-0997279

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

FDA-CBER-2022-1614-0997283

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (19)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:42:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 20 (Day 20)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '30 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '93'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	05 Jan 2021 13:43:08

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.6' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (20)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:43:08

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 21 (Day 21)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '31 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.8' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

FDA-CBER-2022-1614-0997327

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (21)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:44:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 22 (Day 22)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '01 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

FDA-CBER-2022-1614-0997339

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '90'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.7' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

FDA-CBER-2022-1614-0997347

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

FDA-CBER-2022-1614-0997349

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (22)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:45:06

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 23 (Day 23)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '02 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '90'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.8' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

FDA-CBER-2022-1614-0997368

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

FDA-CBER-2022-1614-0997377

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

FDA-CBER-2022-1614-0997378

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

FDA-CBER-2022-1614-0997380

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (23)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:02

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 24 (Day 24)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '03 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '93'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.6' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

FDA-CBER-2022-1614-0997389

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

FDA-CBER-2022-1614-0997390

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Not Done (Not Done)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

FDA-CBER-2022-1614-0997392

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

FDA-CBER-2022-1614-0997393

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

FDA-CBER-2022-1614-0997395

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

FDA-CBER-2022-1614-0997397

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

FDA-CBER-2022-1614-0997399

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

FDA-CBER-2022-1614-0997402

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (24)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:46:59

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 25 (Day 25)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '04 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997405

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '90'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997407

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	05 Jan 2021 13:47:46

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.8' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997409

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997412

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Not Done (Not Done)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997413

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997415

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997417

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997418

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997419

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997421

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997422

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997423

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997424

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (25)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Jan 2021 13:47:46

FDA-CBER-2022-1614-0997425

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 26 (Day 26)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '05 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

FDA-CBER-2022-1614-0997427

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

FDA-CBER-2022-1614-0997428

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

FDA-CBER-2022-1614-0997429

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	08 Jan 2021 17:45:44

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.8' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

FDA-CBER-2022-1614-0997435

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

FDA-CBER-2022-1614-0997436

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

FDA-CBER-2022-1614-0997437

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

FDA-CBER-2022-1614-0997445

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (26)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:45:44

FDA-CBER-2022-1614-0997447

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 27 (Day 27)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997448

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '06 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '92'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997452

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.6' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997455

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997456

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997457

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997458

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997459

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997460

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997462

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997465

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997467

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997468

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (27)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:47:10

FDA-CBER-2022-1614-0997469

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 28 (Day 28)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997470

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '07 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997472

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '94'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997474

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered '98.6' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997477

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997478

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997479

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997480

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997481

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997482

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997484

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997485

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997486

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997487

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997488

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997489

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997490

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (28)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:57:31
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	08 Jan 2021 17:48:11

FDA-CBER-2022-1614-0997491

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 29 (Day 29)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '08 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997494

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '94'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997496

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '98.6' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997497

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997499

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997500

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997501

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997502

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997503

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997507

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997509

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997510

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997511

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997512

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (29)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:30:50

FDA-CBER-2022-1614-0997513

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 30 (Day 30)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997514

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '09 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997516

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '95'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997517

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997518

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '98.6' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997519

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997520

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997521

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997522

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997523

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997524

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997525

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997526

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997527

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997528

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997529

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997531

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997533

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (30)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:32:11

FDA-CBER-2022-1614-0997535

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 31 (Day 31)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '10 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997537

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997538

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '95'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997540

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '98.2' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997541

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997543

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997544

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997545

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997546

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997547

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997548

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997549

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997553

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997555

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (31)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:33:09

FDA-CBER-2022-1614-0997557

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 32 (Day 32)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '11 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997559

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '95'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997561

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997562

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '98.6' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997563

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997565

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997567

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997569

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997572

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997573

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

FDA-CBER-2022-1614-0997577

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (32)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:34:43

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Day 33 (Day 33)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '12 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

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US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '99'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '%'	System	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered '98.1' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

FDA-CBER-2022-1614-0997585

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'Mild (Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

FDA-CBER-2022-1614-0997588

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

FDA-CBER-2022-1614-0997589

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

FDA-CBER-2022-1614-0997590

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

FDA-CBER-2022-1614-0997591

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Symptom Log (33)
Generated On: 11 Aug 2021 22:46:20
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:23
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:17:40
User entered 'None (None)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:36:58

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
User entered '15 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
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)	06 Jan 2021 11:58:34
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 'updated' (Site from System).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:06:49
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:06:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:06:43
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	23 Dec 2020 21:06:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:06:43
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 21:04:55
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

FDA-CBER-2022-1614-0997604

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
User entered '15 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

FDA-CBER-2022-1614-0997609

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:52:35
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:04:55

FDA-CBER-2022-1614-0997610

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: COVID Diagnostic Test
Generated On: 11 Aug 2021 22:46:20
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:30
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	23 Dec 2020 21:06:43

FDA-CBER-2022-1614-0997611

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997615

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Did the subject have Heart Rate ≥ 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:08:36
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:36
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:14
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997617

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997618

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Heart Rate

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User closed query 'Please revisit response as numerous O2 sats ≤ 93% were noted in the symptom log between 23Dec2020 and 06Jan2020.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 20:20:57
Query 'Please revisit response as numerous O2 sats ≤ 93% were noted in the symptom log between 23Dec2020 and 06Jan2020.' answered with 'updated to the lowest O2 level reported during this timeframe.' (Site from CRA).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:52:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:51:39
User opened query 'Please revisit response as numerous O2 sats ≤ 93% were noted in the symptom log between 23Dec2020 and 06Jan2020.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 23:15:09
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:08:36
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:36
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:14
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered '23 Dec 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:51:39
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997621

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered '06 Jan 2021' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:51:39
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered '86' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:51:39
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997623

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:08:36
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:36
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:14
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997625

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997626

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997627

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:08:36
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:36
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:14
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997628

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997629

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:08:36
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:36
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:14
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997630

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
High-Flow Oxygen?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997632

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997636

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997637

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Mechanical Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997638

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997639

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997640

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
ECMO?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997641

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997642

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997643

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
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)	15 Feb 2021 15:38:52
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:54:39
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:54:31
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 22:27:41
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997644

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997645

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997646

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Evidence of Shock Requires Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997647

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997648

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997649

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Acute Renal Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 20:11:06
User closed query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 13:43:28
Query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:45
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:31
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:31
User opened query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:48:13
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997650

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997651

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Hepatic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 20:11:06
User closed query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 13:43:31
Query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:51
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:31
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:31
User opened query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:48:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997653

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Neurologic Dysfunction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 20:11:06
User closed query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 13:43:33
Query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:57
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:31
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:31
User opened query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:48:27
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997655

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Clinical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:54:31
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997656

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997657

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Radiographical Evidence

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 20:11:06
User closed query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 13:43:36
Query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:13:02
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:31
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:12:31
User opened query 'Per CDM: A Yes or No response is required for this question, please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:48:36
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Date of Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997659

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Admission to an intensive care unit due to SARS-CoV-2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:08:36
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:36
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:08:14
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997660

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
Start Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997661

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Covid-19 Severity Assessment
Generated On: 11 Aug 2021 22:46:20
End Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:46
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:07
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:08:14

FDA-CBER-2022-1614-0997662

US3452232
Folder: Covid-19 Assessment 11 Dec 2020
Form: Generate Next COVID-19 Assessment
Generated On: 11 Aug 2021 22:46:20
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:44:30
Data hard unlocked.	(b) (4), (b) (6)	28 Apr 2021 19:53:54
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:21:20
User closed query 'Please clarify if this should be no since no other COVID issues.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 20:21:18
Query 'Please clarify if this should be no since no other COVID issues.' answered with 'updated' (Site from CRA).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:55:20
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:55:13
User opened query 'Please clarify if this should be no since no other COVID issues.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 20:54:09
DataPoint Un-verified.	(b) (4), (b) (6)	29 Jan 2021 20:53:28
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:53:22
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:50:35

FDA-CBER-2022-1614-0997663

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:20
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User accepted default value 'Day 3 (Day 3)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997664

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:20
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997665

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 19:48:36
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:22:43
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' answered with 'updated. accession number 1F619459666' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:56:59
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:56:52
User entered '18 Dec 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:56:52
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:56:24
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:55:49
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:57:07

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:27:42
User entered '17 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997667

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:20
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User accepted default value 'Day 5 (Day 5)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997668

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:20
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997669

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 19:48:43
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:22:43
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' answered with 'updated. accession number 1F619459666' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:57:29
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:57:25
User entered '20 Dec 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:57:25
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:56:33
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19DEC2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:56:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19DEC2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:57:18

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19DEC2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:27:58
User entered '19 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997671

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:20
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User accepted default value 'Day 7 (Day 7)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997672

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:20
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997673

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:22:43
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:57:39
User entered '22 Dec 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:57:39
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User entered '21 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997674

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:20
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User accepted default value 'Day 9 (Day 9)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997675

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:20
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997676

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:22:43
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:57:47
User entered '24 Dec 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:57:47
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User entered '23 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997677

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:20
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User accepted default value 'Day 14 (Day 14)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997678

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:20
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:02:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:02:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:02:19
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 20:59:27
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997679

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:22:43
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	05 Feb 2021 19:58:07
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:58:07
User entered '29 Dec 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:58:07
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
Comment added 'updated'.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:57:56
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	23 Dec 2020 21:02:19
User entered '28 Dec 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:02:19
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997680

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:20
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User accepted default value 'Day 21 (Day 21)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997681

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:20
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:02:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:02:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:02:19
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 20:59:27
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997682

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:18:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Please confirm the year part of "date of Collection" if it needs to be 2021.Thanks ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:14:59
Query 'Per GCL Lab Reconciliation: Saliva: Please confirm the year part of "date of Collection" if it needs to be 2021.Thanks ' answered with 'corrected' (Site from DM).	April Green (b) (4) (b) (4)	05 Apr 2021 15:02:41
DataPoint Un-verified.	April Green (b) (4) (b) (4)	05 Apr 2021 15:02:21
User entered '05 Jan 2021' reason for change: Data Entry Error	April Green (b) (4) (b) (4)	05 Apr 2021 15:02:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Please confirm the year part of "date of Collection" if it needs to be 2021.Thanks ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:09:42
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05JAN2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 18:23:01
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05JAN2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 04:31:56
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 19:48:57

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:22:43
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' answered with 'updated. accession number 1F619459666' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:58:23
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:58:17
User entered '05 Jan 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:58:17
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:56:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04JAN2020 is recorded under Illness Visit Day 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:56:45
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04JAN2020 is recorded under Illness Visit Day 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:58:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04JAN2020 is recorded under Illness Visit Day 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:27:03

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
User entered '04 Jan 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:02:19
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

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US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:20
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User accepted default value 'Day 28 (Day 28)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

FDA-CBER-2022-1614-0997686

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:20
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:02:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:02:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:02:19
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 20:59:27
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

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US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 19:49:03
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:22:43
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' answered with 'updated. accession number 1F619459666' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:58:58
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:58:53
User entered '12 Jan 2021' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:58:53
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1; Please provide accession number for reference.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:56:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2020 is recorded under Illness Visit Day 28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:56:59
User entered '11 Jan 2021' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:58:41

FDA-CBER-2022-1614-0997688

US3452232
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2020 is recorded under Illness Visit Day 28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:58:31
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2020 is recorded under Illness Visit Day 28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:27:20
User entered '11 Jan 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:02:19
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 20:59:27

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US3452232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:54:21
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection Page, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 00:15:22
Query 'Per ETRTR: Please complete data entry in Saliva Collection Page, thanks.' answered with 'updated' (Site from CRA).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:09:42
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection Page, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 23:00:08
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:01:20

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US3452232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:54:21
User entered '15 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:01:20

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US3452232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
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 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:54:21
User entered 'Clinic (Clinic)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:01:20

US3452232
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'SICKD1'	System	15 Dec 2020 21:01:20

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US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997694

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered '15 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997695

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered '11:08'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997696

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '15 Dec 2020 11:08'	System	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997697

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered '68.0' in	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14
DataPoint set to visible.	System	15 Dec 2020 21:01:20

FDA-CBER-2022-1614-0997698

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered '178.4' lb	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14
DataPoint set to visible.	System	15 Dec 2020 21:01:20

FDA-CBER-2022-1614-0997699

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered '98.4' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997700

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered 'Oral (Oral)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997701

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997702

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered '82'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997703

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'bpm'	System	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997704

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User closed query 'Per ETRTR: Please confirm Clinical Significance and add Adverse Event if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 20:21:43
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
Query 'Per ETRTR: Please confirm Clinical Significance and add Adverse Event if applicable, thanks.' answered with 'NCS per P.I.' (Site from CRA).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:03:14
User opened query 'Per ETRTR: Please confirm Clinical Significance and add Adverse Event if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 22:59:45
User entered '20'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'breaths/min'	System	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997706

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered '146'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997707

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'mmHg'	System	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997708

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:24
User entered '93'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997709

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'mmHg'	System	15 Dec 2020 21:02:14

FDA-CBER-2022-1614-0997710

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997711

US3452232
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997712

US3452232
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:37
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:25

FDA-CBER-2022-1614-0997713

US3452232
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:37
User entered '15 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:25

FDA-CBER-2022-1614-0997714

US3452232
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:20
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:42
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:34

US3452232
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:42
User entered '15 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:02:34

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:52
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:53:35

FDA-CBER-2022-1614-0997717

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:52
User entered '12 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:53:35

FDA-CBER-2022-1614-0997718

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
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 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:52
User entered 'Clinic (Clinic)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:53:35

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 11 Aug 2021 22:46:20
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'SICKD28'	System	13 Jan 2021 02:53:35

FDA-CBER-2022-1614-0997720

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997721

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '12 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997722

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '12:54'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997723

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '12 Jan 2021 12:54'	System	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997724

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '68.0' in	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52
DataPoint set to visible.	System	13 Jan 2021 02:53:35

FDA-CBER-2022-1614-0997725

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '191.8' lb	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52
DataPoint set to visible.	System	13 Jan 2021 02:53:35

FDA-CBER-2022-1614-0997726

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '98.1' F	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997727

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered 'Oral (Oral)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997728

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997729

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '100'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997730

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'bpm'	System	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997731

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '16'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997732

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'breaths/min'	System	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997733

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '128'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997734

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'mmHg'	System	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997735

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:55:58
User entered '82'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997736

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered 'mmHg'	System	13 Jan 2021 02:54:52

FDA-CBER-2022-1614-0997737

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997738

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 11 Aug 2021 22:46:20
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997739

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:56:07
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:55:09

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US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 11 Aug 2021 22:46:20
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:56:07
User entered '12 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:55:09

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US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:20
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:56:17
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:55:21

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 10:43:25
Query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'sample was collected on 12JAN2021, Requisition number1F619459666' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:46:19
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:56:17
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 04:49:53

US3452232
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 11 Aug 2021 22:46:20
Date of Collection

Audit	User	Time (GMT)
User entered '12 Jan 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	13 Jan 2021 02:55:21

US3452232
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 11 Aug 2021 22:46:20
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 17:34:33
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:05:19

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:32
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:39
User entered 'USA-US208-2020-mRNA-1273-P301000013'	System	16 Dec 2020 15:41:34
User entered 'New'	(b) (4), (b) (6)	16 Dec 2020 15:41:34

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:35
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
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)	15 Dec 2020 21:09:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 21:09:53
Data point term sent to Coder	System	15 Dec 2020 21:09:02
User entered 'Covid-19'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997747

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 22:07:03
User closed query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:48:34
Query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:11:51
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:11:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	17 Feb 2021 21:11:41
User opened query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 16:57:52
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:41
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997748

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:38
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997749

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:44
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '11 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997751

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:48
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997752

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered empty.	System	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997753

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:43:59
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:51
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997754

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User closed query 'PV Query: COVID-19 symptoms logs are provided through 07 Jan 2021 but the event end date is provided as 12 Jan 2021. Was the subject symptomatic between 07 Jan 2021 and 11 Jan 2021 and are there additional COVID-19 logs available for 8 Jan 2021 to 11 Jan 2021?' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 16:31:56
Query 'PV Query: COVID-19 symptoms logs are provided through 07 Jan 2021 but the event end date is provided as 12 Jan 2021. Was the subject symptomatic between 07 Jan 2021 and 11 Jan 2021 and are there additional COVID-19 logs available for 8 Jan 2021 to 11 Jan 2021?' answered with 'updated' (Site from Safety).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	30 Mar 2021 15:54:57
User opened query 'PV Query: COVID-19 symptoms logs are provided through 07 Jan 2021 but the event end date is provided as 12 Jan 2021. Was the subject symptomatic between 07 Jan 2021 and 11 Jan 2021 and are there additional COVID-19 logs available for 8 Jan 2021 to 11 Jan 2021?' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:37:20
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
User closed query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 20:30:26
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
Query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' answered with 'updated' (Site from Safety).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:44:06
User entered '12 Jan 2021' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:43:59
DataPoint Un-verified.	(b) (4), (b) (6) 1)	02 Feb 2021 15:53:55
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User opened query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:25:03

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:53:57
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997757

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered empty.	System	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997758

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:54:00
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997759

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:54:03
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997760

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997761

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997762

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997763

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997764

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997765

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997766

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997767

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997768

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'Not Related (NOT RELATED)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997771

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'Not Related (NOT RELATED)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered 'Not Applicable (NOT APPLICABLE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '1'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997775

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

FDA-CBER-2022-1614-0997776

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
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 Feb 2021 20:30:36
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:23:23
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 'updated' (Site from Safety).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:44:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	05 Feb 2021 19:43:59
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:54:10
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
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)	22 Dec 2020 14:25:23
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	13 Mar 2021 17:17:18
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:59
User closed query 'PV Query: Please provide the test results for the SARS-CoV-2 RT-PCR nasopharyngeal swab performed on 15 Dec 2020' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:12:52
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 20:12:50
Query 'PV Query: Please provide the test results for the SARS-CoV-2 RT-PCR nasopharyngeal swab performed on 15 Dec 2020' answered with 'updated' (Site from Safety).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:07:24
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'There are none at this time and will be added later if there are any.' (Site from Safety).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:06:19
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:25:46
User opened query 'PV Query: Please provide the test results for the SARS-CoV-2 RT-PCR nasopharyngeal swab performed on 15 Dec 2020' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:24:33

US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Narrative

Audit	User	Time (GMT)
User entered 'Subject was contacted about diary entry. he stated that his wife tested positive for covid 11DEC2020. he stated that he started having some nasal congestion but that was it. He was currently out of town when we spoke and stated he would be back on 14DEC2020 late. He was asked to come in on Tuesday 15DEC2020 which he did.'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '0'	System	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	17 Feb 2021 21:11:41
User entered '0'	System	15 Dec 2020 21:08:40

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US3452232
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 11 Aug 2021 22:46:20
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

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US3452232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
User closed query 'Per DM CLR: Per Diary Dose 2 Day 6, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:23:35
Query 'Per DM CLR: Per Diary Dose 2 Day 6, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Subject did not take any conmeds for this indicaiton.' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	25 Mar 2021 19:03:47
User opened query 'Per DM CLR: Per Diary Dose 2 Day 6, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 20:07:53
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:11
User closed query 'Per ETRTR: Please add Medication dosing details for COVID-19 AE, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Jan 2021 17:52:04
Query 'Per ETRTR: Please add Medication dosing details for COVID-19 AE, thanks.' answered with 'There are none so far and will be updated if there are any later.' (Site from CRA).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	23 Dec 2020 21:04:34

US3452232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:46:20

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

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please add Medication dosing details for COVID-19 AE, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 22:58:45
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:07:10

US3452232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:46:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 00:37:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 00:37:20
Data point term sent to Coder	System	17 Aug 2020 19:09:23
User entered 'FAMOTIDINE'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'INTERMITTENT HEARTBURN'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '20'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	24 Aug 2020 16:14:57
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 16:14:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 16:14:47
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	24 Aug 2020 16:14:47
User entered 'once daily (QD)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	24 Aug 2020 16:14:47
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 19:08:29
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty; reason for change Data Entry Error	Kim Calloway (b) (4) (b) (4)	24 Aug 2020 16:14:57
User entered 'O'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:12:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 19:08:29
User entered 'UN UNK 2017'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '0'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	24 Aug 2020 16:14:47
User entered empty.	System	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	24 Aug 2020 16:14:47
User entered empty.	System	17 Aug 2020 19:08:29

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US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 11 Aug 2021 22:46:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '804 (804)'	System	24 Aug 2020 16:14:47
User entered empty.	System	17 Aug 2020 19:08:29

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US3452232

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:46:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:11:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 19:11:18
Data point term sent to Coder	System	17 Aug 2020 19:10:29
User entered 'MONTELUKAST'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997805

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'INTERMITTENT SEASONAL ALLERGIES'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997806

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '10'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997807

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997809

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'once daily (QD)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997810

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997811

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997812

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997813

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 02:12:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 19:10:05
User entered 'UN UNK 2018'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997814

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '0'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997815

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997816

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997817

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	17 Aug 2020 19:10:05

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997819

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997820

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 11 Aug 2021 22:46:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '804 (804)'	System	17 Aug 2020 19:10:05

FDA-CBER-2022-1614-0997821

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:54:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:54:17
Data point term sent to Coder	System	29 Dec 2020 14:53:12
User entered 'dexamethasone'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997822

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997823

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'Covid-19'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997824

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '6'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997825

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'mg (mg)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997826

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997827

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'once daily (QD)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997828

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997829

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'Oral (ORAL)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997831

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '23 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997832

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997833

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:24:37
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Destiny Heinzig-Cartwright (b) (4) (b) (4)	25 Mar 2021 18:57:20
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	25 Mar 2021 18:56:28
User entered 'No (N)' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	25 Mar 2021 18:56:28
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:54:51
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Un-verified.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	25 Mar 2021 18:56:28
User entered '28 Dec 2020' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	25 Mar 2021 18:56:28
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997835

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997836

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997837

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '1'	System	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997838

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 11 Aug 2021 22:46:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '804 (804)'	System	29 Dec 2020 14:52:39

FDA-CBER-2022-1614-0997839

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User coded data point as ATC: ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS, ATC: ANTHELMINTICS, ATC: ANTINEMATODAL AGENTS, ATC: AVERMECTINES, PRODUCT: IVERMECTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:55:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:55:18
Data point term sent to Coder	System	29 Dec 2020 14:54:13
User entered 'ivermectin'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997840

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997841

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'covid-19'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997842

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '200'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997843

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'ug (ug)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997844

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997845

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'once (ONCE)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997846

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997847

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'Oral (ORAL)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997848

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997849

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '23 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997850

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '0'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997851

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997852

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered '23 Dec 2020'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997853

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:13:09
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 20:24:36
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997854

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered empty.	System	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997855

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered empty.	System	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997856

US3452232
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 11 Aug 2021 22:46:20
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered empty.	System	29 Dec 2020 14:53:36

FDA-CBER-2022-1614-0997857

US3452232
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 11 Aug 2021 22:46:20
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'No (N)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	04 Feb 2021 18:40:22

FDA-CBER-2022-1614-0997858

US3452232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:20
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:57:30
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered '22 Feb 2021'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:23:05

FDA-CBER-2022-1614-0997859

US3452232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:20
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:57:30
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:23:05

US3452232

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:46:20

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 15:57:30
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	22 Feb 2021 22:23:34
User entered 'Subject stated that his work schedule has increased so much that he is unable to come.' reason for change: Data Entry Error	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:23:34
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	22 Feb 2021 22:23:05
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:23:05

US3452232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:20
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:57:30
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:23:05

FDA-CBER-2022-1614-0997862

US3452232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:20
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:57:30
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:23:05

FDA-CBER-2022-1614-0997863

US3452232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:20
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:57:30
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:23:05

FDA-CBER-2022-1614-0997864

US3452232
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 11 Aug 2021 22:46:20
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:57:30
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
User entered empty.	Destiny Heinzig-Cartwright (b) (4) (b) (4)	22 Feb 2021 22:23:05

FDA-CBER-2022-1614-0997865

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'USA-US208-2020-MRNA-1273-P301000013'	System	16 Dec 2020 15:41:34

FDA-CBER-2022-1614-0997866

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Carl'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Griffin'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '3555 NW 58th Stret'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'OKC'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997878

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '73112'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 20:13:17
User entered 'US'	System	16 Dec 2020 15:42:00

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '5'	System	31 Mar 2021 17:11:48
User entered '4'	System	18 Feb 2021 14:06:52
User entered '3'	System	17 Feb 2021 20:32:06
User entered '2'	System	29 Dec 2020 20:13:27
User entered '1'	System	16 Dec 2020 15:42:00

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'USA-US208-2020-MRNA-1273-P301000013'	System	16 Dec 2020 15:41:34

FDA-CBER-2022-1614-0997882

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Carl'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Griffin'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '3555 NW 58th Stret'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'OKC'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997894

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '73112'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 20:13:17
User entered 'US'	System	16 Dec 2020 15:42:00

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '5'	System	31 Mar 2021 17:11:48
User entered '4'	System	18 Feb 2021 14:06:52
User entered '3'	System	17 Feb 2021 20:32:06
User entered '2'	System	29 Dec 2020 20:13:27
User entered '1'	System	16 Dec 2020 15:42:00

FDA-CBER-2022-1614-0997897

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (1)
Generated On: 11 Aug 2021 22:46:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
User entered '16/Dec/2020 10:41'	System	16 Dec 2020 15:42:00

FDA-CBER-2022-1614-0997898

US3452232

Folder: SAE USA-US208-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 20:13:17
User entered '1'	(b) (4), (b) (6)	16 Dec 2020 15:42:00

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'USA-US208-2020-MRNA-1273-P301000013'	System	16 Dec 2020 15:41:34

FDA-CBER-2022-1614-0997900

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Carl'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Griffin'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '3555 NW 58th Stret'	System	17 Feb 2021 20:32:06

FDA-CBER-2022-1614-0997910

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'OKC'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997912

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '73112'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 20:13:17
User entered 'US'	System	16 Dec 2020 15:42:00

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '5'	System	31 Mar 2021 17:11:48
User entered '4'	System	18 Feb 2021 14:06:52
User entered '3'	System	17 Feb 2021 20:32:06
User entered '2'	System	29 Dec 2020 20:13:27
User entered '1'	System	16 Dec 2020 15:42:00

FDA-CBER-2022-1614-0997915

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (2)
Generated On: 11 Aug 2021 22:46:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 20:48:19
User entered '29/Dec/2020 20:13'	System	29 Dec 2020 20:13:27

FDA-CBER-2022-1614-0997916

US3452232

Folder: SAE USA-US208-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 20:31:51
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
User entered '1'	(b) (4), (b) (6)	29 Dec 2020 20:13:27

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'USA-US208-2020-MRNA-1273-P301000013'	System	16 Dec 2020 15:41:34

FDA-CBER-2022-1614-0997918

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

FDA-CBER-2022-1614-0997919

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Carl'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Griffin'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '3555 NW 58th Stret'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'OKC'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997930

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '73112'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 20:13:17
User entered 'US'	System	16 Dec 2020 15:42:00

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '5'	System	31 Mar 2021 17:11:48
User entered '4'	System	18 Feb 2021 14:06:52
User entered '3'	System	17 Feb 2021 20:32:06
User entered '2'	System	29 Dec 2020 20:13:27
User entered '1'	System	16 Dec 2020 15:42:00

FDA-CBER-2022-1614-0997933

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (3)
Generated On: 11 Aug 2021 22:46:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 22:06:49
User entered '17/Feb/2021 15:32'	System	17 Feb 2021 20:32:06

US3452232

Folder: SAE USA-US208-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '1'	(b) (4), (b) (6)	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'USA-US208-2020-MRNA-1273-P301000013'	System	16 Dec 2020 15:41:34

FDA-CBER-2022-1614-0997936

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

FDA-CBER-2022-1614-0997938

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Carl'	System	17 Feb 2021 20:32:06

FDA-CBER-2022-1614-0997944

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Griffin'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '3555 NW 58th Stret'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'OKC'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997948

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '73112'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 20:13:17
User entered 'US'	System	16 Dec 2020 15:42:00

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '5'	System	31 Mar 2021 17:11:48
User entered '4'	System	18 Feb 2021 14:06:52
User entered '3'	System	17 Feb 2021 20:32:06
User entered '2'	System	29 Dec 2020 20:13:27
User entered '1'	System	16 Dec 2020 15:42:00

FDA-CBER-2022-1614-0997951

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (4)
Generated On: 11 Aug 2021 22:46:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 22:06:49
User entered '18/Feb/2021 09:06'	System	18 Feb 2021 14:06:52

US3452232

Folder: SAE USA-US208-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '1'	(b) (4), (b) (6)	18 Feb 2021 14:06:52

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'USA-US208-2020-MRNA-1273-P301000013'	System	16 Dec 2020 15:41:34

FDA-CBER-2022-1614-0997954

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 15:41:48
User entered 'No (N)'	System	16 Dec 2020 15:41:34

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Carl'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'Griffin'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '3555 NW 58th Stret'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered 'OKC'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49

FDA-CBER-2022-1614-0997966

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:05
User entered '73112'	System	17 Feb 2021 20:32:06

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:43:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:13:15
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:13:09
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 20:48:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 20:13:17
User entered 'US'	System	16 Dec 2020 15:42:00

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form
Generated On: 11 Aug 2021 22:46:20
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User entered '5'	System	31 Mar 2021 17:11:48
User entered '4'	System	18 Feb 2021 14:06:52
User entered '3'	System	17 Feb 2021 20:32:06
User entered '2'	System	29 Dec 2020 20:13:27
User entered '1'	System	16 Dec 2020 15:42:00

FDA-CBER-2022-1614-0997969

US3452232
Folder: SAE USA-US208-2020-MRNA-1273-P301000013
Form: Safety Report Form (5)
Generated On: 11 Aug 2021 22:46:20
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:18:02
User entered '31/Mar/2021 13:11'	System	31 Mar 2021 17:11:48

FDA-CBER-2022-1614-0997970

US3452232

Folder: SAE USA-US208-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:46:20

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)	28 Apr 2021 00:53:49
User signature succeeded.	Carl Griffin (b) (4) (b) (4)	16 Apr 2021 03:43:42
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:18:02
User entered '1'	(b) (4), (b) (6)	31 Mar 2021 17:11:48