US3112221 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

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US3112221
Form: Participant Creation
Data signed: (b) (4) **05 Mar 2021 19:17:45**
Generated On: 09 Jun 2021 15:10:42

Participant ID	US3112221

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0515464

US3112221
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515465

US3112221
Folder: Screening
Form: Demographics
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Date of Birth (MMM yyyy)	(b) (6) 1972
Age	48
Age Units	YEARS
Age (Derived)	48
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-2022-1614-0515466

US3112221
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Date of Informed Consent *(dd MMM yyyy)*	12 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-2022-1614-0515467

US3112221
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515468

US3112221
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0515469

US3112221
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Condition	COLON CANCER
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)	UN APR 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	APR 2018
Stop Year (derived)	2018

FDA-CBER-2022-1614-0515470

US3112221
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Condition	BILATERAL HANDS ECZEMA
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0515471

US3112221
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Condition	KIDNEY STONES
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)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

FDA-CBER-2022-1614-0515472

US3112221
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Condition	COLON CANCER RESECTION
Start date (dd MMM yyyy)	UN APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes No
If No, please specify the stop date (dd MMM yyyy)	UN APR 2018
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	APR 2018
Stop Year (derived)	2018

US3112221
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	12 AUG 2020
Time of assessment *(00:00-23:59)*	15:48 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 15:48
Height *(xxx.x)*	70.5 in
Weight *(xxx.x)*	205 lb
BMI *(xxx.x)*	29.05932 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-2022-1614-0515474

US3112221
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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

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

FDA-CBER-2022-1614-0515475

US3112221
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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

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

US3112221
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **05 Mar 2021 19:17:48**
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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

FDA-CBER-2022-1614-0515477

US3112221
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0515478

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

What was the date of randomization? *(dd MMM yyyy)*	12 AUG 2020
What was the participant's randomization number?	103693
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ■ >=18 and <65 years and at risk ☐ >=65 years ☐

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

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

FDA-CBER-2022-1614-0515479

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0515480

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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)*	12 AUG 2020
Time of assessment *(00:00-23:59)*	15:48 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 15:48
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	101 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	086 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0515481

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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)*	12 AUG 2020
Time of assessment *(00:00-23:59)*	17:41 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 17:41
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ● Axillary ○ Other ○
If Other, specify	
Pulse *(xxx)*	88 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	088 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0515482

US3112221
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Was the physical examination performed? Yes ☐ No ☒

Date of examination *(dd MMM yyyy)* _____

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

FDA-CBER-2022-1614-0515483

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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)*	12 AUG 2020
What was the treatment time? *(00:00-23:59)*	17:05 (24 HR)
Treatment Date and Time (derived)	12 AUG 2020 17:05
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-2022-1614-0515484

US3112221
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	12 AUG 2020
Collection time *(00:00-23:59)*	16:03 (24 HR)
Collection date and time (derived)	12 AUG 2020 16:03

FDA-CBER-2022-1614-0515485

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Collection date *(dd MMM yyyy)*			12 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:37	12 AUG 2020 15:37
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0515486

US3112221
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515487

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 AUG 2020 17:42
PC Open Date & Time	12 AUG 2020 17:25
PC Close Date & Time	12 AUG 2020 19:55

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.5 °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	12 AUG 2020 20:52
PC Open Date & Time	12 AUG 2020 20:50
PC Close Date & Time	13 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 AUG 2020 18:37
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °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	14 AUG 2020 18:08
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	15 AUG 2020 13:58
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.0 °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	16 AUG 2020 14:27
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42

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**	98.2 °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	17 AUG 2020 18:21
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 13:32
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42

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	12 AUG 2020 17:43
PC Open Date & Time	12 AUG 2020 17:25
PC Close Date & Time	12 AUG 2020 19:55

FDA-CBER-2022-1614-0515496

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42

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	12 AUG 2020 20:53
PC Open Date & Time	12 AUG 2020 20:50
PC Close Date & Time	13 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42

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	13 AUG 2020 18:37
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0515498

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42

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	14 AUG 2020 18:08
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0515499

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42

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	15 AUG 2020 13:58
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0515500

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42

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	16 AUG 2020 14:28
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42

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	17 AUG 2020 18:21
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42

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	18 AUG 2020 13:32
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 AUG 2020 17:43
PC Open Date & Time	12 AUG 2020 17:25
PC Close Date & Time	12 AUG 2020 19:55

FDA-CBER-2022-1614-0515505

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 ☐

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	12 AUG 2020 20:53
PC Open Date & Time	12 AUG 2020 20:50
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0515507

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 ■

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42

	Yes ☐
PC Time stamp	13 AUG 2020 18:38
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0515509

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 ■

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42

	Yes ☐
PC Time stamp	14 AUG 2020 18:09
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0515511

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 ■

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42

	Yes ☐
PC Time stamp	15 AUG 2020 13:58
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0515513

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 ■

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42

	Yes
PC Time stamp	16 AUG 2020 14:28
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0515515

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 ■

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42

	Yes
PC Time stamp	17 AUG 2020 18:21
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0515517

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 ■

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42

	Yes ☐
PC Time stamp	18 AUG 2020 13:33
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0515519

US3112221
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515520

US3112221
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515521

US3112221
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515522

US3112221
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515523

US3112221
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 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-2022-1614-0515524

US3112221
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515525

US3112221
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0515526

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	16:26 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 16:26
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	087 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0515527

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	17:47 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 17:47
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	086 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0515528

US3112221
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	8 SEP 2020

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

FDA-CBER-2022-1614-0515529

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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)*	8 SEP 2020
What was the treatment time? *(00:00-23:59)*	17:12 (24 HR)
Treatment Date and Time (derived)	8 SEP 2020 17:12
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-2022-1614-0515530

US3112221
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	8 SEP 2020
Collection time *(00:00-23:59)*	16:40 (24 HR)
Collection date and time (derived)	8 SEP 2020 16:40

FDA-CBER-2022-1614-0515531

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Collection date *(dd MMM yyyy)*			8 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:35	8 SEP 2020 16:35
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0515532

US3112221
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515533

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 17:49
PC Open Date & Time	08 SEP 2020 17:32
PC Close Date & Time	08 SEP 2020 20:02

FDA-CBER-2022-1614-0515534

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 21:14
PC Open Date & Time	08 SEP 2020 20:57
PC Close Date & Time	09 SEP 2020 11:59

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 SEP 2020 20:43
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	10 SEP 2020 19:57
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 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**	97.9 °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 00:00
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 SEP 2020 12:05
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 SEP 2020 12:00
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	15 SEP 2020 04:39
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42

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 17:50
PC Open Date & Time	08 SEP 2020 17:32
PC Close Date & Time	08 SEP 2020 20:02

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42

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 21:14
PC Open Date & Time	08 SEP 2020 20:57
PC Close Date & Time	09 SEP 2020 11:59

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42

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 20:43
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42

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 19:58
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0515545

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515546

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42

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	12 SEP 2020 12:05
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-0515547

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515548

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42

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 04:39
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	08 SEP 2020 17:50
PC Open Date & Time	08 SEP 2020 17:32
PC Close Date & Time	08 SEP 2020 20:02

FDA-CBER-2022-1614-0515551

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 ☐

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	08 SEP 2020 21:14
PC Open Date & Time	08 SEP 2020 20:57
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-0515553

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515554

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42

	Yes
PC Time stamp	09 SEP 2020 20:43
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-0515555

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 ■

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42

	Yes
PC Time stamp	10 SEP 2020 19:58
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0515557

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 ■

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42

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

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

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42

	Yes ☐
PC Time stamp	12 SEP 2020 12:05
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-0515561

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 ■

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42

	Yes
PC Time stamp	15 SEP 2020 04:39
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0515565

US3112221
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515566

US3112221
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515567

US3112221
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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*	

US3112221
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515569

US3112221
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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*	

US3112221
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515571

US3112221
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0515572

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	6 OCT 2020
Time of assessment *(00:00-23:59)*	14:06 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 14:06
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	88 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0515573

US3112221
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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

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

US3112221
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	6 OCT 2020
Collection time *(00:00-23:59)*	14:15 (24 HR)
Collection date and time (derived)	6 OCT 2020 14:15

FDA-CBER-2022-1614-0515575

US3112221
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:48**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515576

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 13:09:44
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	19 OCT 2020 00:12:38
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

FDA-CBER-2022-1614-0515578

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	26 OCT 2020 01:15:11
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

FDA-CBER-2022-1614-0515579

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	09 NOV 2020 03:56:18
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

FDA-CBER-2022-1614-0515580

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

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 18:07:25
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

FDA-CBER-2022-1614-0515583

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	27 NOV 2020 01:48:34
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

FDA-CBER-2022-1614-0515584

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	True
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 ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	06 DEC 2020 12:15:40
Patient Cloud Open Date & Time	04 DEC 2020 00:01

Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	11 DEC 2020 02:57:37
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

FDA-CBER-2022-1614-0515587

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 03:00:16
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

FDA-CBER-2022-1614-0515588

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	25 DEC 2020 02:37:21
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

FDA-CBER-2022-1614-0515589

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	01 JAN 2021 05:06:55
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

FDA-CBER-2022-1614-0515590

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	08 JAN 2021 02:25:39
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	15 JAN 2021 01:11:31
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

FDA-CBER-2022-1614-0515592

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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 ☐
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):	
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	22 JAN 2021 05:00:21
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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 ☐
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):	
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	29 JAN 2021 03:35:43
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42

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	05 FEB 2021 00:58:39
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3112221
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 15:10:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		17 MAR 2021 01:57:22

FDA-CBER-2022-1614-0515596

US3112221
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	02 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0515597

US3112221
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515598

US3112221
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was Contact Attempted?	Yes ☐ No ■
Date of Contact or Contact Attempt *(dd MMM yyyy)*	
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	NOT CONDUCTED DUE TO ILLNESS VISITS

FDA-CBER-2022-1614-0515599

US3112221
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515600

US3112221
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 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-2022-1614-0515601

US3112221
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515602

US3112221
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 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-2022-1614-0515603

US3112221
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515604

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID-19 Contact
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

Date of Contact	07 DEC 2020
Time of Contact	08:33
Date and Time of Contact (derived)	07 DEC 2020 08:33
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-2022-1614-0515605

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515606

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	30 NOV 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515610

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	01 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515614

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	02 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515618

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	03 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515622

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	04 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515626

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	05 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515630

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	06 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515634

	Day 33 ☐ Day 34 ☐ Day 35 ☐ Day 36 ☐ Day 37 ☐ Day 38 ☐ Day 39 ☐ Day 40 ☐
Date	07 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	97.8 F
Chills	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Cough	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Shortness of Breath	None ■ Mild ☐ Moderate ☐ Severe ☐ Not Done ☐
Difficulty Breathing	None ■ Mild ☐ Moderate ☐ Severe ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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	08 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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 DEC 2020
Assessment Not Done	False
O2 Saturation	98 %
O2 Saturation Units	%
Temperature	96.8 F
Chills	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ■
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ■
	Mild ☐
	Moderate ☐
	Severe ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515646

	Day 33 ☐
	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	10 DEC 2020
Assessment Not Done	False
O2 Saturation	99 %
O2 Saturation Units	%
Temperature	97.1 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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

	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 ☐

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

Date of Visit	07 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	07 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)	0

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

Generate Next COVID-19 Assessment	Yes ☐ No ■

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US3112221
Folder: Illness Visit (1)
Form: Saliva Collection
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	09 DEC 2020
Day 5	Yes	11 DEC 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

FDA-CBER-2022-1614-0515652

US3112221
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	07 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SICKD1

FDA-CBER-2022-1614-0515653

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	07 DEC 2020
Time of assessment *(00:00-23:59)*	10:22 (24 HR)
Vital Signs Date and Time (derived)	07 DEC 2020 10:22
Height *(xxx.x)*	ND - Not Done
Weight *(xxx.x)*	ND - Not Done
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0515654

US3112221
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

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

FDA-CBER-2022-1614-0515655

US3112221
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ■ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	07 DEC 2020

FDA-CBER-2022-1614-0515656

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515657

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515658

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

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

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

FDA-CBER-2022-1614-0515659

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515660

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0515661

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **12 Mar 2021 16:34:06**
Generated On: 09 Jun 2021 15:10:42

Date of updated informed consent *(dd MMM yyyy)*	6 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	9 FEB 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ■
Actual Dose 1	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	1
Continuing with mRNA-1273	

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	9 FEB 2021
Collection time *(00:00-23:59)*	10:15 (24 HR)
Collection date and time (derived)	9 FEB 2021 10:15

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

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

FDA-CBER-2022-1614-0515664

US3112221
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

Did the participant experience any adverse events?

Yes ■
No ☐

If Yes, enter details on the Adverse Events form.

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **05 Mar 2021 19:17:45**
Generated On: 09 Jun 2021 15:10:42

AEID	
Adverse event	VIRAL SYNDROME
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)*	30 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	08 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **05 Mar 2021 19:17:45**
Generated On: 09 Jun 2021 15:10:42

AEID	USA-US062-2021-MRNA-1273-P30 1000010
Adverse event	METASTATIC STAGE 4 COLORECTAL CARCINOMA
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)*	19 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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

Narrative

	REPORTED NEW MALIGNANCY, STAGE AND EXTENT NOT DETERMINED. PT. REPORTED UPDATE ON COLORECTAL CARCINOMA, DIAGNOSIS OF STAGE 4, METASTASIZED TO BILATERAL LUNGS. UPDATED GRADE AND SAE CRITERIA.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

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

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

FDA-CBER-2022-1614-0515671

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

Name of Medication	NYQUIL LIQUID (ACETAMINOPHEN, DEXTROMETHORPHAN HBR, DOXYLAMINE SUCCINATE)
Prophylaxis	Yes ☐ No ■
Indication	VIRAL SYNDROME
Dose per administration	30
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	Q6HRS
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)*	04 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	07 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 ☐

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **23 Apr 2021 21:03:08**
Generated On: 09 Jun 2021 15:10:42

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ■
Indication	VIRAL SYNDROME
Dose per administration	400
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	08 DEC 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3112221
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **05 Mar 2021 19:17:46**
Generated On: 09 Jun 2021 15:10:42

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0515676

US3112221
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 15:10:42

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-2022-1614-0515677

US3112221
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

Date of study discontinuation/completion *(dd MMM yyyy)*	09 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	PATIENT DECISION TO WITHDRAW CONSENT AS CONTINUED PARTICIPATION/VACCINATION WILL BE COMPLICATED WITH UPCOMING MOVE TO RECEIVE TREATMENT OF RECENT COLORECTAL CANCER DIAGNOSIS.
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-2022-1614-0515678

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

SAEID	USA-US062-2021-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form (1)
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

SAEID	USA-US062-2021-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/FEB/2021 08:14
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

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form (2)
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

SAEID	USA-US062-2021-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/FEB/2021 11:32
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

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form (3)
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

SAEID	USA-US062-2021-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/FEB/2021 10:11
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

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form (4)
Data signed: (b) (4) **05 Mar 2021 19:17:47**
Generated On: 09 Jun 2021 15:10:42

SAEID	USA-US062-2021-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/FEB/2021 14:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3112221 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112221
Form: Participant Creation
Generated On: 09 Jun 2021 15:10:42
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'US3112221'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 22:59:09

FDA-CBER-2022-1614-0515685

US3112221
Form: Participant Creation
Generated On: 09 Jun 2021 15:10:42

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25

FDA-CBER-2022-1614-0515686

US3112221
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:12:53

FDA-CBER-2022-1614-0515687

US3112221
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 22:59:10

FDA-CBER-2022-1614-0515688

US3112221
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:12:53

FDA-CBER-2022-1614-0515689

US3112221
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'SCRN'	System	13 Aug 2020 00:12:53

FDA-CBER-2022-1614-0515690

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered (b) (6) 1972'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 22:59:12

FDA-CBER-2022-1614-0515691

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '48'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515692

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'YEARS'	System	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515693

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '48'	System	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515694

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Male (M)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515695

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515696

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '1'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515697

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515698

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515699

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515700

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515701

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515702

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515703

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515704

US3112221
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:10:42
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:39

FDA-CBER-2022-1614-0515705

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 Aug 2020'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515706

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'Aug 2020'	System	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515707

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '2020'	System	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515708

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Amendment 2 (2)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515709

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515710

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515711

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515712

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:02

FDA-CBER-2022-1614-0515713

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 22:59:10

FDA-CBER-2022-1614-0515714

US3112221
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:10:42
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '1'	System	13 Aug 2020 00:13:07

FDA-CBER-2022-1614-0515715

US3112221
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 15:10:42
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:07

FDA-CBER-2022-1614-0515716

US3112221
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 15:10:42
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:01:57
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:39:45

FDA-CBER-2022-1614-0515717

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colon cancer, LLT: Colon cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 22:19:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 22:19:42
Data point term sent to Coder	System	15 Feb 2021 22:03:39
User entered 'colon cancer'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515718

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:23
User entered 'un UNK 2018'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515719

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:23
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515720

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:23
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515721

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:23
User entered 'un Apr 2018'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515722

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:23
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515723

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'Jan 2018'	System	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515724

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '2018'	System	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515725

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'Apr 2018'	System	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515726

US3112221
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:10:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '2018'	System	15 Feb 2021 22:02:50

FDA-CBER-2022-1614-0515727

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 22:05:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 22:05:41
Data point term sent to Coder	System	15 Feb 2021 22:04:40
User entered 'bilateral hands eczema'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515728

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'un UNK 2008'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515729

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515730

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515731

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515732

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515733

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'Jan 2008'	System	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515734

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '2008'	System	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515735

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered empty.	System	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515736

US3112221
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:10:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered empty.	System	15 Feb 2021 22:03:41

FDA-CBER-2022-1614-0515737

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 22:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 22:05:42
Data point term sent to Coder	System	15 Feb 2021 22:04:42
User entered 'kidney stones'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515738

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'un UNK 2010'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515739

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515740

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515741

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'un UNK 2010'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515742

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515743

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'Jan 2010'	System	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515744

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '2010'	System	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515745

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'Jan 2010'	System	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515746

US3112221
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:10:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '2010'	System	15 Feb 2021 22:04:12

FDA-CBER-2022-1614-0515747

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cancer surgery, LLT: Cancer surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 22:06:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Feb 2021 22:06:42
Data point term sent to Coder	System	15 Feb 2021 22:05:43
User entered 'colon cancer resection'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515748

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:37
User entered 'un Apr 2018'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515749

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:37
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515750

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:37
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515751

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:37
User entered 'un Apr 2018'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515752

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:20:37
User entered '0'	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:04:57

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'Apr 2018'	System	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515754

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '2018'	System	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515755

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'Apr 2018'	System	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515756

US3112221
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:10:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '2018'	System	15 Feb 2021 22:04:57

FDA-CBER-2022-1614-0515757

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515758

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515759

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '15:48'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515760

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '12 Aug 2020 15:48'	System	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515761

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '70.5' in	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35
DataPoint set to visible.	System	13 Aug 2020 00:13:07

FDA-CBER-2022-1614-0515762

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '205' lb	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35
DataPoint set to visible.	System	13 Aug 2020 00:13:07

FDA-CBER-2022-1614-0515763

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
Amendment Manager: User entered '29.05932'	System	16 Sep 2020 23:54:37
User entered '29.1'	System	18 Aug 2020 19:42:35
DataPoint set to visible.	System	13 Aug 2020 00:13:07

FDA-CBER-2022-1614-0515764

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'kg/m2'	System	18 Aug 2020 19:42:35
DataPoint set to visible.	System	13 Aug 2020 00:13:07

FDA-CBER-2022-1614-0515765

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 10:06:39
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:21:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:21:18
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Aug 2020 15:42:43
User entered '98.5' F	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515766

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:21:18
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515768

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:21:18
User entered '101'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515769

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'bpm'	System	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515770

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:21:18
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515771

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'breaths/min'	System	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515772

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:21:18
User entered '127'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515773

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515774

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:21:18
User entered '086'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515775

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	18 Aug 2020 19:42:35

FDA-CBER-2022-1614-0515776

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37

FDA-CBER-2022-1614-0515777

US3112221
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37

FDA-CBER-2022-1614-0515778

US3112221
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:10

FDA-CBER-2022-1614-0515779

US3112221
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
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 14:15:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 00:28:44
User entered '12 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:10

FDA-CBER-2022-1614-0515780

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515781

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515782

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515783

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515784

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515785

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515786

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515787

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515788

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515789

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515790

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515792

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515793

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515794

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515795

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515796

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515797

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '1'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515798

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515799

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515800

US3112221
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:10:42
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:40

FDA-CBER-2022-1614-0515801

US3112221
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:56

FDA-CBER-2022-1614-0515802

US3112221
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:56

FDA-CBER-2022-1614-0515803

US3112221
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:43:56

FDA-CBER-2022-1614-0515804

US3112221
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'VISIT1'	System	18 Aug 2020 19:43:56

FDA-CBER-2022-1614-0515805

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:10:42
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 23:09:10

FDA-CBER-2022-1614-0515806

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:10:42
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:03:31
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:03:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 23:09:10
User entered '103693' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 23:09:10

FDA-CBER-2022-1614-0515807

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:10:42
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 23:09:10

FDA-CBER-2022-1614-0515808

US3112221

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:44:32

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:44:32

FDA-CBER-2022-1614-0515810

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:10:42
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:44:32

FDA-CBER-2022-1614-0515811

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:10:42
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:44:32

FDA-CBER-2022-1614-0515812

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:10:42
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:44:32

FDA-CBER-2022-1614-0515813

US3112221
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:10:42
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:20:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:55:38

FDA-CBER-2022-1614-0515814

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:10:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515815

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:10:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515816

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:10:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515817

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:10:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515818

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515819

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515820

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515821

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '15:48'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515822

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '12 Aug 2020 15:48'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515823

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '98.5' F	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515824

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515825

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515826

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '101'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515827

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'bpm'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515828

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515829

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'breaths/min'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515830

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '127'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515831

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515832

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '086'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515833

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515834

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:10:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515835

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:10:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515836

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515837

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515838

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515839

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:03:27
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	18 Aug 2020 19:45:42
User entered '17:41'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515840

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '12 Aug 2020 17:41'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515841

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '97.8' F	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515842

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515843

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515844

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '88'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515845

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'bpm'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515846

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515847

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'breaths/min'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515848

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '136'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515849

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515850

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '088'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515851

US3112221
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	18 Aug 2020 19:45:42

FDA-CBER-2022-1614-0515852

US3112221
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:52

FDA-CBER-2022-1614-0515853

US3112221
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:45:52

FDA-CBER-2022-1614-0515854

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515855

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515856

US3112221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:23

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515858

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 Aug 2020'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515859

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '17:05'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515860

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '12 Aug 2020 17:05'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515861

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Left Arm (LEFT ARM)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515862

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'ONCE'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515863

US3112221
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515864

US3112221
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:11

FDA-CBER-2022-1614-0515865

US3112221
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:11

FDA-CBER-2022-1614-0515866

US3112221
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16:03'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:11

FDA-CBER-2022-1614-0515867

US3112221
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '12 Aug 2020 16:03'	System	18 Aug 2020 19:46:11

FDA-CBER-2022-1614-0515868

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:10:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '12 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515869

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:10:42
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515870

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515871

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '15:37'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515872

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:10:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '12 Aug 2020 15:37'	System	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515873

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:10:42
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515874

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515875

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515876

US3112221
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:10:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered empty.	System	18 Aug 2020 19:46:32

FDA-CBER-2022-1614-0515877

US3112221
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:46:38

FDA-CBER-2022-1614-0515878

US3112221
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '1'	System	18 Aug 2020 19:46:38

FDA-CBER-2022-1614-0515879

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515880

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:41:46', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '67891133-b944-4598-8b56-6e5deefbada9'	System	13 Aug 2020 00:42:14
User entered 'Yes (Y)'	System	13 Aug 2020 00:42:14

FDA-CBER-2022-1614-0515881

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:41:56', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '67891133-b944-4598-8b56-6e5deefbada9'	System	13 Aug 2020 00:42:14
User entered '97.8'	System	13 Aug 2020 00:42:14

FDA-CBER-2022-1614-0515882

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:42:07', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '67891133-b944-4598-8b56-6e5deefbada9'	System	13 Aug 2020 00:42:14
User entered 'No (N)'	System	13 Aug 2020 00:42:14

FDA-CBER-2022-1614-0515883

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:42:12', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '67891133-b944-4598-8b56-6e5deefbada9'	System	13 Aug 2020 00:42:14
User entered '12 Aug 2020 17:42'	System	13 Aug 2020 00:42:14

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 17:25'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515885

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515886

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515887

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:52:06', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'a4047157-cf51-436b-b581-9677c85a524a'	System	13 Aug 2020 03:52:22
User entered 'Yes (Y)'	System	13 Aug 2020 03:52:22

FDA-CBER-2022-1614-0515888

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:52:11', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'a4047157-cf51-436b-b581-9677c85a524a'	System	13 Aug 2020 03:52:22
User entered '96.5'	System	13 Aug 2020 03:52:22

FDA-CBER-2022-1614-0515889

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:52:15', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'a4047157-cf51-436b-b581-9677c85a524a'	System	13 Aug 2020 03:52:22
User entered 'No (N)'	System	13 Aug 2020 03:52:22

FDA-CBER-2022-1614-0515890

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:52:18', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'a4047157-cf51-436b-b581-9677c85a524a'	System	13 Aug 2020 03:52:22
User entered '12 Aug 2020 20:52'	System	13 Aug 2020 03:52:22

FDA-CBER-2022-1614-0515891

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 20:50'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515892

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515893

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 2'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515894

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:13', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '8078e8c5-925f-4318-8773-dd36d746e802'	System	14 Aug 2020 01:37:33
User entered 'Yes (Y)'	System	14 Aug 2020 01:37:33

FDA-CBER-2022-1614-0515895

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:18', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '8078e8c5-925f-4318-8773-dd36d746e802'	System	14 Aug 2020 01:37:33
User entered '97.8'	System	14 Aug 2020 01:37:33

FDA-CBER-2022-1614-0515896

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:26', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '8078e8c5-925f-4318-8773-dd36d746e802'	System	14 Aug 2020 01:37:33
User entered 'No (N)'	System	14 Aug 2020 01:37:33

FDA-CBER-2022-1614-0515897

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:30', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '8078e8c5-925f-4318-8773-dd36d746e802'	System	14 Aug 2020 01:37:33
User entered '13 Aug 2020 18:37'	System	14 Aug 2020 01:37:33

FDA-CBER-2022-1614-0515898

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515899

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515900

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 3'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515901

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:07:01', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3d1d1468-09af-4db8-82b3-5d8ea976ba78'	System	15 Aug 2020 01:08:10
User entered 'Yes (Y)'	System	15 Aug 2020 01:08:10

FDA-CBER-2022-1614-0515902

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:07:55', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3d1d1468-09af-4db8-82b3-5d8ea976ba78'	System	15 Aug 2020 01:08:10
User entered '97.9'	System	15 Aug 2020 01:08:10

FDA-CBER-2022-1614-0515903

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:02', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3d1d1468-09af-4db8-82b3-5d8ea976ba78'	System	15 Aug 2020 01:08:10
User entered 'No (N)'	System	15 Aug 2020 01:08:10

FDA-CBER-2022-1614-0515904

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:08', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3d1d1468-09af-4db8-82b3-5d8ea976ba78'	System	15 Aug 2020 01:08:10
User entered '14 Aug 2020 18:08'	System	15 Aug 2020 01:08:10

FDA-CBER-2022-1614-0515905

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515906

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515907

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 4'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515908

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:57:29', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'eeebcf8b-624d-4693-8445-bc9aadcc5e7a'	System	15 Aug 2020 20:58:09
User entered 'Yes (Y)'	System	15 Aug 2020 20:58:09

FDA-CBER-2022-1614-0515909

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:57:58', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'eeebcf8b-624d-4693-8445-bc9aadcc5e7a'	System	15 Aug 2020 20:58:09
User entered '96.6'	System	15 Aug 2020 20:58:09

FDA-CBER-2022-1614-0515910

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'eeebcf8b-624d-4693-8445-bc9aadcc5e7a'	System	15 Aug 2020 20:58:09
User entered 'No (N)'	System	15 Aug 2020 20:58:09

FDA-CBER-2022-1614-0515911

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:06', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'eeebcf8b-624d-4693-8445-bc9aadcc5e7a'	System	15 Aug 2020 20:58:09
User entered '15 Aug 2020 13:58'	System	15 Aug 2020 20:58:09

FDA-CBER-2022-1614-0515912

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515913

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515914

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 5'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515915

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:27:27', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '55ddebc5-9207-4e16-94fa-fe6828d84773'	System	16 Aug 2020 21:27:52
User entered 'Yes (Y)'	System	16 Aug 2020 21:27:52

FDA-CBER-2022-1614-0515916

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:27:40', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '55ddebc5-9207-4e16-94fa-fe6828d84773'	System	16 Aug 2020 21:27:52
User entered '97.0'	System	16 Aug 2020 21:27:52

FDA-CBER-2022-1614-0515917

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:27:43', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '55ddebc5-9207-4e16-94fa-fe6828d84773'	System	16 Aug 2020 21:27:52
User entered 'No (N)'	System	16 Aug 2020 21:27:52

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:27:50', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '55ddebc5-9207-4e16-94fa-fe6828d84773'	System	16 Aug 2020 21:27:52
User entered '16 Aug 2020 14:27'	System	16 Aug 2020 21:27:52

FDA-CBER-2022-1614-0515919

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515920

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515921

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 6'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515922

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:20:52', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '693b06ea-bf01-4d15-9f44-1ae37598dca7'	System	18 Aug 2020 01:21:14
User entered 'Yes (Y)'	System	18 Aug 2020 01:21:14

FDA-CBER-2022-1614-0515923

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '693b06ea-bf01-4d15-9f44-1ae37598dca7'	System	18 Aug 2020 01:21:14
User entered '98.2'	System	18 Aug 2020 01:21:14

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:07', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '693b06ea-bf01-4d15-9f44-1ae37598dca7'	System	18 Aug 2020 01:21:14
User entered 'No (N)'	System	18 Aug 2020 01:21:14

FDA-CBER-2022-1614-0515925

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:10', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '693b06ea-bf01-4d15-9f44-1ae37598dca7'	System	18 Aug 2020 01:21:14
User entered '17 Aug 2020 18:21'	System	18 Aug 2020 01:21:14

FDA-CBER-2022-1614-0515926

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515927

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515928

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 7'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515929

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:23', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '597b5f20-15d1-468b-9156-96d402845466'	System	18 Aug 2020 20:32:34
User entered 'Yes (Y)'	System	18 Aug 2020 20:32:34

FDA-CBER-2022-1614-0515930

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:26', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '597b5f20-15d1-468b-9156-96d402845466'	System	18 Aug 2020 20:32:34
User entered '98.1'	System	18 Aug 2020 20:32:34

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:29', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '597b5f20-15d1-468b-9156-96d402845466'	System	18 Aug 2020 20:32:34
User entered 'No (N)'	System	18 Aug 2020 20:32:34

FDA-CBER-2022-1614-0515932

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '597b5f20-15d1-468b-9156-96d402845466'	System	18 Aug 2020 20:32:34
User entered '18 Aug 2020 13:32'	System	18 Aug 2020 20:32:34

FDA-CBER-2022-1614-0515933

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515934

US3112221
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515935

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515936

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:42:57', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6b2f085b-17f9-437e-8650-32b587f77104'	System	13 Aug 2020 00:43:24
User entered 'None (1)'	System	13 Aug 2020 00:43:24

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:00', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6b2f085b-17f9-437e-8650-32b587f77104'	System	13 Aug 2020 00:43:24
User entered 'No (N)'	System	13 Aug 2020 00:43:24

FDA-CBER-2022-1614-0515938

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:02', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6b2f085b-17f9-437e-8650-32b587f77104'	System	13 Aug 2020 00:43:24
User entered 'No (N)'	System	13 Aug 2020 00:43:24

FDA-CBER-2022-1614-0515939

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:19', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6b2f085b-17f9-437e-8650-32b587f77104'	System	13 Aug 2020 00:43:24
User entered 'None (1)'	System	13 Aug 2020 00:43:24

FDA-CBER-2022-1614-0515940

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6b2f085b-17f9-437e-8650-32b587f77104'	System	13 Aug 2020 00:43:24
User entered '12 Aug 2020 17:43'	System	13 Aug 2020 00:43:24

FDA-CBER-2022-1614-0515941

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 17:25'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515942

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515943

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515944

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:52:29', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '155d9e14-2345-490d-ac15-e700ecef8761'	System	13 Aug 2020 03:53:35
User entered 'None (1)'	System	13 Aug 2020 03:53:35

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:52:54', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '155d9e14-2345-490d-ac15-e700ecef8761'	System	13 Aug 2020 03:53:35
User entered 'No (N)'	System	13 Aug 2020 03:53:35

FDA-CBER-2022-1614-0515946

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:16', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '155d9e14-2345-490d-ac15-e700ecef8761'	System	13 Aug 2020 03:53:35
User entered 'No (N)'	System	13 Aug 2020 03:53:35

FDA-CBER-2022-1614-0515947

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:25', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '155d9e14-2345-490d-ac15-e700ecef8761'	System	13 Aug 2020 03:53:35
User entered 'None (1)'	System	13 Aug 2020 03:53:35

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '155d9e14-2345-490d-ac15-e700ecef8761'	System	13 Aug 2020 03:53:35
User entered '12 Aug 2020 20:53'	System	13 Aug 2020 03:53:35

FDA-CBER-2022-1614-0515949

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 20:50'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515950

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515951

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 2'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515952

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:39', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3ef4fb31-4d19-4ea8-b1b8-77bf42e5ff30'	System	14 Aug 2020 01:37:51
User entered 'None (1)'	System	14 Aug 2020 01:37:51

FDA-CBER-2022-1614-0515953

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:41', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3ef4fb31-4d19-4ea8-b1b8-77bf42e5ff30'	System	14 Aug 2020 01:37:51
User entered 'No (N)'	System	14 Aug 2020 01:37:51

FDA-CBER-2022-1614-0515954

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:43', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3ef4fb31-4d19-4ea8-b1b8-77bf42e5ff30'	System	14 Aug 2020 01:37:51
User entered 'No (N)'	System	14 Aug 2020 01:37:51

FDA-CBER-2022-1614-0515955

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:47', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3ef4fb31-4d19-4ea8-b1b8-77bf42e5ff30'	System	14 Aug 2020 01:37:51
User entered 'None (1)'	System	14 Aug 2020 01:37:51

FDA-CBER-2022-1614-0515956

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:49', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3ef4fb31-4d19-4ea8-b1b8-77bf42e5ff30'	System	14 Aug 2020 01:37:51
User entered '13 Aug 2020 18:37'	System	14 Aug 2020 01:37:51

FDA-CBER-2022-1614-0515957

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515958

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515959

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 3'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515960

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:17', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1f8837be-62e5-46ec-bce1-955312ddd39b'	System	15 Aug 2020 01:08:48
User entered 'None (1)'	System	15 Aug 2020 01:08:48

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:20', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1f8837be-62e5-46ec-bce1-955312ddd39b'	System	15 Aug 2020 01:08:48
User entered 'No (N)'	System	15 Aug 2020 01:08:48

FDA-CBER-2022-1614-0515962

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:26', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1f8837be-62e5-46ec-bce1-955312ddd39b'	System	15 Aug 2020 01:08:48
User entered 'No (N)'	System	15 Aug 2020 01:08:48

FDA-CBER-2022-1614-0515963

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1f8837be-62e5-46ec-bce1-955312ddd39b'	System	15 Aug 2020 01:08:48
User entered 'None (1)'	System	15 Aug 2020 01:08:48

FDA-CBER-2022-1614-0515964

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:34', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1f8837be-62e5-46ec-bce1-955312ddd39b'	System	15 Aug 2020 01:08:48
User entered '14 Aug 2020 18:08'	System	15 Aug 2020 01:08:48

FDA-CBER-2022-1614-0515965

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515966

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515967

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 4'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515968

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:10', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '647eba48-d27b-47a4-b49b-b088b61b9612'	System	15 Aug 2020 20:58:21
User entered 'None (1)'	System	15 Aug 2020 20:58:21

FDA-CBER-2022-1614-0515969

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:13', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '647eba48-d27b-47a4-b49b-b088b61b9612'	System	15 Aug 2020 20:58:21
User entered 'No (N)'	System	15 Aug 2020 20:58:21

FDA-CBER-2022-1614-0515970

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:14', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '647eba48-d27b-47a4-b49b-b088b61b9612'	System	15 Aug 2020 20:58:21
User entered 'No (N)'	System	15 Aug 2020 20:58:21

FDA-CBER-2022-1614-0515971

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:17', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '647eba48-d27b-47a4-b49b-b088b61b9612'	System	15 Aug 2020 20:58:21
User entered 'None (1)'	System	15 Aug 2020 20:58:21

FDA-CBER-2022-1614-0515972

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:19', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '647eba48-d27b-47a4-b49b-b088b61b9612'	System	15 Aug 2020 20:58:21
User entered '15 Aug 2020 13:58'	System	15 Aug 2020 20:58:21

FDA-CBER-2022-1614-0515973

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515974

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515975

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 5'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515976

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:27:55', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '28b5a382-1458-4c86-a6f4-2c8c50cc4d9e'	System	16 Aug 2020 21:28:04
User entered 'None (1)'	System	16 Aug 2020 21:28:04

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:27:57', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '28b5a382-1458-4c86-a6f4-2c8c50cc4d9e'	System	16 Aug 2020 21:28:04
User entered 'No (N)'	System	16 Aug 2020 21:28:04

FDA-CBER-2022-1614-0515978

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:27:58', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '28b5a382-1458-4c86-a6f4-2c8c50cc4d9e'	System	16 Aug 2020 21:28:04
User entered 'No (N)'	System	16 Aug 2020 21:28:04

FDA-CBER-2022-1614-0515979

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:00', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '28b5a382-1458-4c86-a6f4-2c8c50cc4d9e'	System	16 Aug 2020 21:28:04
User entered 'None (1)'	System	16 Aug 2020 21:28:04

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:02', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '28b5a382-1458-4c86-a6f4-2c8c50cc4d9e'	System	16 Aug 2020 21:28:04
User entered '16 Aug 2020 14:28'	System	16 Aug 2020 21:28:04

FDA-CBER-2022-1614-0515981

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515982

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515983

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 6'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515984

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:13', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '63d2fd42-df3d-4ae0-9ba8-68c5d7c3ae14'	System	18 Aug 2020 01:21:22
User entered 'None (1)'	System	18 Aug 2020 01:21:22

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:15', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '63d2fd42-df3d-4ae0-9ba8-68c5d7c3ae14'	System	18 Aug 2020 01:21:22
User entered 'No (N)'	System	18 Aug 2020 01:21:22

FDA-CBER-2022-1614-0515986

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:16', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '63d2fd42-df3d-4ae0-9ba8-68c5d7c3ae14'	System	18 Aug 2020 01:21:22
User entered 'No (N)'	System	18 Aug 2020 01:21:22

FDA-CBER-2022-1614-0515987

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:18', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '63d2fd42-df3d-4ae0-9ba8-68c5d7c3ae14'	System	18 Aug 2020 01:21:22
User entered 'None (1)'	System	18 Aug 2020 01:21:22

FDA-CBER-2022-1614-0515988

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:20', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '63d2fd42-df3d-4ae0-9ba8-68c5d7c3ae14'	System	18 Aug 2020 01:21:22
User entered '17 Aug 2020 18:21'	System	18 Aug 2020 01:21:22

FDA-CBER-2022-1614-0515989

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515990

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515991

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 7'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515992

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:34', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '71c5546f-3607-4e2f-87bb-36a2ecf9eba5'	System	18 Aug 2020 20:32:45
User entered 'None (1)'	System	18 Aug 2020 20:32:45

FDA-CBER-2022-1614-0515993

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:36', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '71c5546f-3607-4e2f-87bb-36a2ecf9eba5'	System	18 Aug 2020 20:32:45
User entered 'No (N)'	System	18 Aug 2020 20:32:45

FDA-CBER-2022-1614-0515994

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:38', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '71c5546f-3607-4e2f-87bb-36a2ecf9eba5'	System	18 Aug 2020 20:32:45
User entered 'No (N)'	System	18 Aug 2020 20:32:45

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:40', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '71c5546f-3607-4e2f-87bb-36a2ecf9eba5'	System	18 Aug 2020 20:32:45
User entered 'None (1)'	System	18 Aug 2020 20:32:45

FDA-CBER-2022-1614-0515996

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:42', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '71c5546f-3607-4e2f-87bb-36a2ecf9eba5'	System	18 Aug 2020 20:32:45
User entered '18 Aug 2020 13:32'	System	18 Aug 2020 20:32:45

FDA-CBER-2022-1614-0515997

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515998

US3112221
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0515999

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516000

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5063dd9e-9d7d-4ec7-b181-78ef745689be'	System	13 Aug 2020 00:43:59
User entered 'None (0)'	System	13 Aug 2020 00:43:59

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5063dd9e-9d7d-4ec7-b181-78ef745689be'	System	13 Aug 2020 00:43:59
User entered 'None (0)'	System	13 Aug 2020 00:43:59

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:38', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5063dd9e-9d7d-4ec7-b181-78ef745689be'	System	13 Aug 2020 00:43:59
User entered 'None (0)'	System	13 Aug 2020 00:43:59

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:41', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5063dd9e-9d7d-4ec7-b181-78ef745689be'	System	13 Aug 2020 00:43:59
User entered 'None (0)'	System	13 Aug 2020 00:43:59

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:45', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5063dd9e-9d7d-4ec7-b181-78ef745689be'	System	13 Aug 2020 00:43:59
User entered 'None (0)'	System	13 Aug 2020 00:43:59

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:47', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5063dd9e-9d7d-4ec7-b181-78ef745689be'	System	13 Aug 2020 00:43:59
User entered 'None (0)'	System	13 Aug 2020 00:43:59

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:55', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5063dd9e-9d7d-4ec7-b181-78ef745689be'	System	13 Aug 2020 00:43:59
User entered 'No (N)'	System	13 Aug 2020 00:43:59

FDA-CBER-2022-1614-0516007

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T17:43:57', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5063dd9e-9d7d-4ec7-b181-78ef745689be'	System	13 Aug 2020 00:43:59
User entered '12 Aug 2020 17:43'	System	13 Aug 2020 00:43:59

FDA-CBER-2022-1614-0516008

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 17:25'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516009

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 19:55'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516010

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516011

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2ec75d6f-c97e-4682-936d-1a10fcf44178'	System	13 Aug 2020 03:53:57
User entered 'None (0)'	System	13 Aug 2020 03:53:57

FDA-CBER-2022-1614-0516012

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:37', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2ec75d6f-c97e-4682-936d-1a10fcf44178'	System	13 Aug 2020 03:53:57
User entered 'None (0)'	System	13 Aug 2020 03:53:57

FDA-CBER-2022-1614-0516013

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:38', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2ec75d6f-c97e-4682-936d-1a10fcf44178'	System	13 Aug 2020 03:53:57
User entered 'None (0)'	System	13 Aug 2020 03:53:57

FDA-CBER-2022-1614-0516014

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:39', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2ec75d6f-c97e-4682-936d-1a10fcf44178'	System	13 Aug 2020 03:53:57
User entered 'None (0)'	System	13 Aug 2020 03:53:57

FDA-CBER-2022-1614-0516015

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:41', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2ec75d6f-c97e-4682-936d-1a10fcf44178'	System	13 Aug 2020 03:53:57
User entered 'None (0)'	System	13 Aug 2020 03:53:57

FDA-CBER-2022-1614-0516016

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:43', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2ec75d6f-c97e-4682-936d-1a10fcf44178'	System	13 Aug 2020 03:53:57
User entered 'None (0)'	System	13 Aug 2020 03:53:57

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:51', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2ec75d6f-c97e-4682-936d-1a10fcf44178'	System	13 Aug 2020 03:53:57
User entered 'No (N)'	System	13 Aug 2020 03:53:57

FDA-CBER-2022-1614-0516018

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-12T20:53:54', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2ec75d6f-c97e-4682-936d-1a10fcf44178'	System	13 Aug 2020 03:53:57
User entered '12 Aug 2020 20:53'	System	13 Aug 2020 03:53:57

FDA-CBER-2022-1614-0516019

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Aug 2020 20:50'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516020

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516021

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 2'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516022

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:53', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1cc009d2-1026-495f-818d-3dc06b8e53cb'	System	14 Aug 2020 01:38:17
User entered 'None (0)'	System	14 Aug 2020 01:38:17

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:55', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1cc009d2-1026-495f-818d-3dc06b8e53cb'	System	14 Aug 2020 01:38:17
User entered 'None (0)'	System	14 Aug 2020 01:38:17

FDA-CBER-2022-1614-0516024

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:56', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1cc009d2-1026-495f-818d-3dc06b8e53cb'	System	14 Aug 2020 01:38:17
User entered 'None (0)'	System	14 Aug 2020 01:38:17

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:37:58', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1cc009d2-1026-495f-818d-3dc06b8e53cb'	System	14 Aug 2020 01:38:17
User entered 'None (0)'	System	14 Aug 2020 01:38:17

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:38:00', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1cc009d2-1026-495f-818d-3dc06b8e53cb'	System	14 Aug 2020 01:38:17
User entered 'None (0)'	System	14 Aug 2020 01:38:17

FDA-CBER-2022-1614-0516027

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:38:02', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1cc009d2-1026-495f-818d-3dc06b8e53cb'	System	14 Aug 2020 01:38:17
User entered 'None (0)'	System	14 Aug 2020 01:38:17

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:38:13', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1cc009d2-1026-495f-818d-3dc06b8e53cb'	System	14 Aug 2020 01:38:17
User entered 'No (N)'	System	14 Aug 2020 01:38:17

FDA-CBER-2022-1614-0516029

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-13T18:38:16', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1cc009d2-1026-495f-818d-3dc06b8e53cb'	System	14 Aug 2020 01:38:17
User entered '13 Aug 2020 18:38'	System	14 Aug 2020 01:38:17

FDA-CBER-2022-1614-0516030

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516031

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516032

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 3'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516033

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:42', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5cf9fa03-da9b-47e5-b6b0-03532447c651'	System	15 Aug 2020 01:09:26
User entered 'None (0)'	System	15 Aug 2020 01:09:26

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:47', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5cf9fa03-da9b-47e5-b6b0-03532447c651'	System	15 Aug 2020 01:09:26
User entered 'None (0)'	System	15 Aug 2020 01:09:26

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:51', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5cf9fa03-da9b-47e5-b6b0-03532447c651'	System	15 Aug 2020 01:09:26
User entered 'None (0)'	System	15 Aug 2020 01:09:26

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:55', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5cf9fa03-da9b-47e5-b6b0-03532447c651'	System	15 Aug 2020 01:09:26
User entered 'None (0)'	System	15 Aug 2020 01:09:26

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:08:59', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5cf9fa03-da9b-47e5-b6b0-03532447c651'	System	15 Aug 2020 01:09:26
User entered 'None (0)'	System	15 Aug 2020 01:09:26

FDA-CBER-2022-1614-0516038

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:09:05', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5cf9fa03-da9b-47e5-b6b0-03532447c651'	System	15 Aug 2020 01:09:26
User entered 'None (0)'	System	15 Aug 2020 01:09:26

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:09:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5cf9fa03-da9b-47e5-b6b0-03532447c651'	System	15 Aug 2020 01:09:26
User entered 'No (N)'	System	15 Aug 2020 01:09:26

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-14T18:09:24', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '5cf9fa03-da9b-47e5-b6b0-03532447c651'	System	15 Aug 2020 01:09:26
User entered '14 Aug 2020 18:09'	System	15 Aug 2020 01:09:26

FDA-CBER-2022-1614-0516041

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516042

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516043

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 4'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516044

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '03e00a73-47dc-4703-bce9-19154670e241'	System	15 Aug 2020 20:58:42
User entered 'None (0)'	System	15 Aug 2020 20:58:42

FDA-CBER-2022-1614-0516045

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:25', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '03e00a73-47dc-4703-bce9-19154670e241'	System	15 Aug 2020 20:58:42
User entered 'None (0)'	System	15 Aug 2020 20:58:42

FDA-CBER-2022-1614-0516046

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:27', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '03e00a73-47dc-4703-bce9-19154670e241'	System	15 Aug 2020 20:58:42
User entered 'None (0)'	System	15 Aug 2020 20:58:42

FDA-CBER-2022-1614-0516047

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:29', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '03e00a73-47dc-4703-bce9-19154670e241'	System	15 Aug 2020 20:58:42
User entered 'None (0)'	System	15 Aug 2020 20:58:42

FDA-CBER-2022-1614-0516048

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:30', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '03e00a73-47dc-4703-bce9-19154670e241'	System	15 Aug 2020 20:58:42
User entered 'None (0)'	System	15 Aug 2020 20:58:42

FDA-CBER-2022-1614-0516049

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '03e00a73-47dc-4703-bce9-19154670e241'	System	15 Aug 2020 20:58:42
User entered 'None (0)'	System	15 Aug 2020 20:58:42

FDA-CBER-2022-1614-0516050

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:36', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '03e00a73-47dc-4703-bce9-19154670e241'	System	15 Aug 2020 20:58:42
User entered 'No (N)'	System	15 Aug 2020 20:58:42

FDA-CBER-2022-1614-0516051

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-15T13:58:38', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '03e00a73-47dc-4703-bce9-19154670e241'	System	15 Aug 2020 20:58:42
User entered '15 Aug 2020 13:58'	System	15 Aug 2020 20:58:42

FDA-CBER-2022-1614-0516052

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516053

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516054

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 5'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516055

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:05', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '93e228ad-a5ef-4e8c-8bd1-a832bcfd30ca'	System	16 Aug 2020 21:28:25
User entered 'None (0)'	System	16 Aug 2020 21:28:25

FDA-CBER-2022-1614-0516056

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:07', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '93e228ad-a5ef-4e8c-8bd1-a832bcfd30ca'	System	16 Aug 2020 21:28:25
User entered 'None (0)'	System	16 Aug 2020 21:28:25

FDA-CBER-2022-1614-0516057

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:09', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '93e228ad-a5ef-4e8c-8bd1-a832bcfd30ca'	System	16 Aug 2020 21:28:25
User entered 'None (0)'	System	16 Aug 2020 21:28:25

FDA-CBER-2022-1614-0516058

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:11', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '93e228ad-a5ef-4e8c-8bd1-a832bcfd30ca'	System	16 Aug 2020 21:28:25
User entered 'None (0)'	System	16 Aug 2020 21:28:25

FDA-CBER-2022-1614-0516059

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:12', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '93e228ad-a5ef-4e8c-8bd1-a832bcfd30ca'	System	16 Aug 2020 21:28:25
User entered 'None (0)'	System	16 Aug 2020 21:28:25

FDA-CBER-2022-1614-0516060

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:14', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '93e228ad-a5ef-4e8c-8bd1-a832bcfd30ca'	System	16 Aug 2020 21:28:25
User entered 'None (0)'	System	16 Aug 2020 21:28:25

FDA-CBER-2022-1614-0516061

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:20', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '93e228ad-a5ef-4e8c-8bd1-a832bcfd30ca'	System	16 Aug 2020 21:28:25
User entered 'No (N)'	System	16 Aug 2020 21:28:25

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-16T14:28:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '93e228ad-a5ef-4e8c-8bd1-a832bcfd30ca'	System	16 Aug 2020 21:28:25
User entered '16 Aug 2020 14:28'	System	16 Aug 2020 21:28:25

FDA-CBER-2022-1614-0516063

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516064

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516065

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 6'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516066

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:23', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bec5954a-cf82-4614-b219-016b527c3921'	System	18 Aug 2020 01:21:43
User entered 'None (0)'	System	18 Aug 2020 01:21:43

FDA-CBER-2022-1614-0516067

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:26', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bec5954a-cf82-4614-b219-016b527c3921'	System	18 Aug 2020 01:21:43
User entered 'None (0)'	System	18 Aug 2020 01:21:43

FDA-CBER-2022-1614-0516068

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:27', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bec5954a-cf82-4614-b219-016b527c3921'	System	18 Aug 2020 01:21:43
User entered 'None (0)'	System	18 Aug 2020 01:21:43

FDA-CBER-2022-1614-0516069

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:28', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bec5954a-cf82-4614-b219-016b527c3921'	System	18 Aug 2020 01:21:43
User entered 'None (0)'	System	18 Aug 2020 01:21:43

FDA-CBER-2022-1614-0516070

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:30', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bec5954a-cf82-4614-b219-016b527c3921'	System	18 Aug 2020 01:21:43
User entered 'None (0)'	System	18 Aug 2020 01:21:43

FDA-CBER-2022-1614-0516071

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bec5954a-cf82-4614-b219-016b527c3921'	System	18 Aug 2020 01:21:43
User entered 'None (0)'	System	18 Aug 2020 01:21:43

FDA-CBER-2022-1614-0516072

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:38', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bec5954a-cf82-4614-b219-016b527c3921'	System	18 Aug 2020 01:21:43
User entered 'No (N)'	System	18 Aug 2020 01:21:43

FDA-CBER-2022-1614-0516073

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-17T18:21:40', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bec5954a-cf82-4614-b219-016b527c3921'	System	18 Aug 2020 01:21:43
User entered '17 Aug 2020 18:21'	System	18 Aug 2020 01:21:43

FDA-CBER-2022-1614-0516074

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516075

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516076

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 7'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516077

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:45', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6cb3d9da-1fa5-4156-9dfb-a89c371a41e5'	System	18 Aug 2020 20:33:07
User entered 'None (0)'	System	18 Aug 2020 20:33:07

FDA-CBER-2022-1614-0516078

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:47', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6cb3d9da-1fa5-4156-9dfb-a89c371a41e5'	System	18 Aug 2020 20:33:07
User entered 'None (0)'	System	18 Aug 2020 20:33:07

FDA-CBER-2022-1614-0516079

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:48', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6cb3d9da-1fa5-4156-9dfb-a89c371a41e5'	System	18 Aug 2020 20:33:07
User entered 'None (0)'	System	18 Aug 2020 20:33:07

FDA-CBER-2022-1614-0516080

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:50', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6cb3d9da-1fa5-4156-9dfb-a89c371a41e5'	System	18 Aug 2020 20:33:07
User entered 'None (0)'	System	18 Aug 2020 20:33:07

FDA-CBER-2022-1614-0516081

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:52', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6cb3d9da-1fa5-4156-9dfb-a89c371a41e5'	System	18 Aug 2020 20:33:07
User entered 'None (0)'	System	18 Aug 2020 20:33:07

FDA-CBER-2022-1614-0516082

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:32:53', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6cb3d9da-1fa5-4156-9dfb-a89c371a41e5'	System	18 Aug 2020 20:33:07
User entered 'None (0)'	System	18 Aug 2020 20:33:07

FDA-CBER-2022-1614-0516083

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:33:00', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6cb3d9da-1fa5-4156-9dfb-a89c371a41e5'	System	18 Aug 2020 20:33:07
User entered 'No (N)'	System	18 Aug 2020 20:33:07

FDA-CBER-2022-1614-0516084

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-08-18T13:33:02', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6cb3d9da-1fa5-4156-9dfb-a89c371a41e5'	System	18 Aug 2020 20:33:07
User entered '18 Aug 2020 13:33'	System	18 Aug 2020 20:33:07

FDA-CBER-2022-1614-0516085

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516086

US3112221
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516087

US3112221
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 00:10:26

FDA-CBER-2022-1614-0516088

US3112221
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 00:10:26

FDA-CBER-2022-1614-0516089

US3112221
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 00:10:26

US3112221
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 00:10:26

FDA-CBER-2022-1614-0516091

US3112221
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 00:10:30

FDA-CBER-2022-1614-0516092

US3112221
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User entered '1'	System	20 Aug 2020 00:10:30

FDA-CBER-2022-1614-0516093

US3112221
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:57:41

FDA-CBER-2022-1614-0516094

US3112221
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:57:41

FDA-CBER-2022-1614-0516095

US3112221
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:57:41

FDA-CBER-2022-1614-0516096

US3112221
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:57:41

FDA-CBER-2022-1614-0516097

US3112221
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 18:57:46

FDA-CBER-2022-1614-0516098

US3112221
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:51:27
User entered '1'	System	26 Aug 2020 18:57:46

FDA-CBER-2022-1614-0516099

US3112221
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:22:37

FDA-CBER-2022-1614-0516100

US3112221
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '2 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:22:37

FDA-CBER-2022-1614-0516101

US3112221
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:22:37

US3112221
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:22:37

FDA-CBER-2022-1614-0516103

US3112221
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 00:28:34

FDA-CBER-2022-1614-0516104

US3112221
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:43
User entered '1'	System	09 Sep 2020 00:28:34

FDA-CBER-2022-1614-0516105

US3112221
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User closed query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:06:53
Query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' answered with 'completed' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:21:53
User opened query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 16:26:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 00:28:44

US3112221
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 10:07:04
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 00:28:44
User entered '8 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 00:28:44

FDA-CBER-2022-1614-0516107

US3112221
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 00:28:44

FDA-CBER-2022-1614-0516108

US3112221
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'VISIT2'	System	09 Sep 2020 00:28:44

FDA-CBER-2022-1614-0516109

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516110

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516111

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '8 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516112

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16:26'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516113

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '8 Sep 2020 16:26'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516114

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '98.5' F	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516115

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516116

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516117

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '78'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516118

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'bpm'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516119

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516120

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'breaths/min'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516121

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '128'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516122

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516123

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '087'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516124

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516125

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516126

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516127

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '8 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516128

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '17:47'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516129

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '8 Sep 2020 17:47'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516130

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '98.0' F	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516131

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516132

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516133

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '80'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516134

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'bpm'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516135

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516136

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'breaths/min'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516137

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '128'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516138

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516139

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '086'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516140

US3112221
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'mmHg'	System	22 Sep 2020 23:15:48

FDA-CBER-2022-1614-0516141

US3112221
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	19 Oct 2020 16:38:35
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:57

FDA-CBER-2022-1614-0516142

US3112221
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '8 Sep 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	19 Oct 2020 16:38:35
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:15:57

FDA-CBER-2022-1614-0516143

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516144

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516145

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42

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 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516146

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516147

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '8 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516148

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '17:12'	(b) (4), (b) (6)	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516149

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '8 Sep 2020 17:12'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516150

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516151

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'ONCE'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516152

US3112221
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:10:42
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516153

US3112221
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:22

FDA-CBER-2022-1614-0516154

US3112221
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '8 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:22

FDA-CBER-2022-1614-0516155

US3112221
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16:40'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:22

FDA-CBER-2022-1614-0516156

US3112221
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '8 Sep 2020 16:40'	System	22 Sep 2020 23:16:22

FDA-CBER-2022-1614-0516157

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:10:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '8 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516158

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:10:42
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516159

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516160

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16:35'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516161

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:10:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '8 Sep 2020 16:35'	System	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516162

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:10:42
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516163

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516164

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516165

US3112221
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:10:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered empty.	System	22 Sep 2020 23:16:40

FDA-CBER-2022-1614-0516166

US3112221
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 00:29:04

FDA-CBER-2022-1614-0516167

US3112221
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:33:37
User entered '1'	System	09 Sep 2020 00:29:04

FDA-CBER-2022-1614-0516168

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516169

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:48:41', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'd979b9ef-f8fd-43fe-a3fa-d3a36ca7a7ab'	System	09 Sep 2020 00:49:04
User entered 'Yes (Y)'	System	09 Sep 2020 00:49:04

FDA-CBER-2022-1614-0516170

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:48:45', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'd979b9ef-f8fd-43fe-a3fa-d3a36ca7a7ab'	System	09 Sep 2020 00:49:04
User entered '98.0'	System	09 Sep 2020 00:49:04

FDA-CBER-2022-1614-0516171

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:48:49', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'd979b9ef-f8fd-43fe-a3fa-d3a36ca7a7ab'	System	09 Sep 2020 00:49:04
User entered 'No (N)'	System	09 Sep 2020 00:49:04

FDA-CBER-2022-1614-0516172

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:49:00', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'd979b9ef-f8fd-43fe-a3fa-d3a36ca7a7ab'	System	09 Sep 2020 00:49:04
User entered '08 Sep 2020 17:49'	System	09 Sep 2020 00:49:04

FDA-CBER-2022-1614-0516173

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 17:32'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516174

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 20:02'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516175

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516176

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:13:57', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb00d8fa-6fea-444c-aeae-ba1a40e6a16b'	System	09 Sep 2020 04:14:10
User entered 'Yes (Y)'	System	09 Sep 2020 04:14:10

FDA-CBER-2022-1614-0516177

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:03', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb00d8fa-6fea-444c-aeae-ba1a40e6a16b'	System	09 Sep 2020 04:14:10
User entered '97.8'	System	09 Sep 2020 04:14:10

FDA-CBER-2022-1614-0516178

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:05', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb00d8fa-6fea-444c-aeae-ba1a40e6a16b'	System	09 Sep 2020 04:14:10
User entered 'No (N)'	System	09 Sep 2020 04:14:10

FDA-CBER-2022-1614-0516179

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:08', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb00d8fa-6fea-444c-aeae-ba1a40e6a16b'	System	09 Sep 2020 04:14:10
User entered '08 Sep 2020 21:14'	System	09 Sep 2020 04:14:10

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 20:57'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516181

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '09 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516182

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 2'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516183

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:14', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'ee6ade6f-6b7c-45d9-ad15-311df48904f2'	System	10 Sep 2020 03:43:26
User entered 'Yes (Y)'	System	10 Sep 2020 03:43:26

FDA-CBER-2022-1614-0516184

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:20', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'ee6ade6f-6b7c-45d9-ad15-311df48904f2'	System	10 Sep 2020 03:43:26
User entered '97.8'	System	10 Sep 2020 03:43:26

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'ee6ade6f-6b7c-45d9-ad15-311df48904f2'	System	10 Sep 2020 03:43:26
User entered 'No (N)'	System	10 Sep 2020 03:43:26

FDA-CBER-2022-1614-0516186

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:24', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'ee6ade6f-6b7c-45d9-ad15-311df48904f2'	System	10 Sep 2020 03:43:26
User entered '09 Sep 2020 20:43'	System	10 Sep 2020 03:43:26

FDA-CBER-2022-1614-0516187

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516188

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516189

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 3'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516190

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:57:45', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9d9c6090-da8d-4e8e-a647-df6d26fdfc45'	System	11 Sep 2020 02:57:58
User entered 'Yes (Y)'	System	11 Sep 2020 02:57:58

FDA-CBER-2022-1614-0516191

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:57:51', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9d9c6090-da8d-4e8e-a647-df6d26fdfc45'	System	11 Sep 2020 02:57:58
User entered '97.6'	System	11 Sep 2020 02:57:58

FDA-CBER-2022-1614-0516192

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:57:53', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9d9c6090-da8d-4e8e-a647-df6d26fdfc45'	System	11 Sep 2020 02:57:58
User entered 'No (N)'	System	11 Sep 2020 02:57:58

FDA-CBER-2022-1614-0516193

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:57:56', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9d9c6090-da8d-4e8e-a647-df6d26fdfc45'	System	11 Sep 2020 02:57:58
User entered '10 Sep 2020 19:57'	System	11 Sep 2020 02:57:58

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516195

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516196

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 4'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516197

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-11T23:59:39', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '92c3230f-3804-476f-98c7-55d044ca7fa0'	System	12 Sep 2020 07:00:03
User entered 'Yes (Y)'	System	12 Sep 2020 07:00:03

FDA-CBER-2022-1614-0516198

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-11T23:59:54', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '92c3230f-3804-476f-98c7-55d044ca7fa0'	System	12 Sep 2020 07:00:03
User entered '97.9'	System	12 Sep 2020 07:00:03

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-11T23:59:58', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '92c3230f-3804-476f-98c7-55d044ca7fa0'	System	12 Sep 2020 07:00:03
User entered 'No (N)'	System	12 Sep 2020 07:00:03

FDA-CBER-2022-1614-0516200

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:01', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '92c3230f-3804-476f-98c7-55d044ca7fa0'	System	12 Sep 2020 07:00:03
User entered '12 Sep 2020 00:00'	System	12 Sep 2020 07:00:03

FDA-CBER-2022-1614-0516201

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516202

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516203

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 5'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516204

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:14', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3698dcbb-a041-4a27-ad09-f65fe84033ab'	System	12 Sep 2020 19:05:30
User entered 'Yes (Y)'	System	12 Sep 2020 19:05:30

FDA-CBER-2022-1614-0516205

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:21', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3698dcbb-a041-4a27-ad09-f65fe84033ab'	System	12 Sep 2020 19:05:30
User entered '97.6'	System	12 Sep 2020 19:05:30

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:25', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3698dcbb-a041-4a27-ad09-f65fe84033ab'	System	12 Sep 2020 19:05:30
User entered 'No (N)'	System	12 Sep 2020 19:05:30

FDA-CBER-2022-1614-0516207

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:27', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3698dcbb-a041-4a27-ad09-f65fe84033ab'	System	12 Sep 2020 19:05:30
User entered '12 Sep 2020 12:05'	System	12 Sep 2020 19:05:30

FDA-CBER-2022-1614-0516208

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516209

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516210

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 6'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516211

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:26', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'cb704b79-534c-4c86-9ede-ece357f1fd0a'	System	13 Sep 2020 19:01:32
User entered 'Yes (Y)'	System	13 Sep 2020 19:01:32

FDA-CBER-2022-1614-0516212

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'cb704b79-534c-4c86-9ede-ece357f1fd0a'	System	13 Sep 2020 19:01:32
User entered '97.8'	System	13 Sep 2020 19:01:32

FDA-CBER-2022-1614-0516213

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'cb704b79-534c-4c86-9ede-ece357f1fd0a'	System	13 Sep 2020 19:01:32
User entered 'No (N)'	System	13 Sep 2020 19:01:32

FDA-CBER-2022-1614-0516214

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:41', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'cb704b79-534c-4c86-9ede-ece357f1fd0a'	System	13 Sep 2020 19:01:32
User entered '13 Sep 2020 12:00'	System	13 Sep 2020 19:01:32

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516216

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516217

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 7'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516218

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:38:48', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6bd5d984-23d5-44c7-8273-80a85286fcbb'	System	15 Sep 2020 11:39:09
User entered 'Yes (Y)'	System	15 Sep 2020 11:39:09

FDA-CBER-2022-1614-0516219

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:38:57', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6bd5d984-23d5-44c7-8273-80a85286fcbb'	System	15 Sep 2020 11:39:09
User entered '97.8'	System	15 Sep 2020 11:39:09

FDA-CBER-2022-1614-0516220

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6bd5d984-23d5-44c7-8273-80a85286fcbb'	System	15 Sep 2020 11:39:09
User entered 'No (N)'	System	15 Sep 2020 11:39:09

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:07', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6bd5d984-23d5-44c7-8273-80a85286fcbb'	System	15 Sep 2020 11:39:09
User entered '15 Sep 2020 04:39'	System	15 Sep 2020 11:39:09

FDA-CBER-2022-1614-0516222

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516223

US3112221
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516224

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516225

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:49:45', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2d87ff97-bdb3-4b0c-8f89-fde3afcd4c95'	System	09 Sep 2020 00:50:16
User entered 'None (1)'	System	09 Sep 2020 00:50:16

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2d87ff97-bdb3-4b0c-8f89-fde3afcd4c95'	System	09 Sep 2020 00:50:16
User entered 'No (N)'	System	09 Sep 2020 00:50:16

FDA-CBER-2022-1614-0516227

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:07', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2d87ff97-bdb3-4b0c-8f89-fde3afcd4c95'	System	09 Sep 2020 00:50:16
User entered 'No (N)'	System	09 Sep 2020 00:50:16

FDA-CBER-2022-1614-0516228

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:12', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2d87ff97-bdb3-4b0c-8f89-fde3afcd4c95'	System	09 Sep 2020 00:50:16
User entered 'None (1)'	System	09 Sep 2020 00:50:16

FDA-CBER-2022-1614-0516229

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:14', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '2d87ff97-bdb3-4b0c-8f89-fde3afcd4c95'	System	09 Sep 2020 00:50:16
User entered '08 Sep 2020 17:50'	System	09 Sep 2020 00:50:16

FDA-CBER-2022-1614-0516230

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 17:32'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516231

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 20:02'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516232

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516233

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:12', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '29a3c543-5340-4066-8ece-5785a3ce6834'	System	09 Sep 2020 04:14:29
User entered 'None (1)'	System	09 Sep 2020 04:14:29

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:17', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '29a3c543-5340-4066-8ece-5785a3ce6834'	System	09 Sep 2020 04:14:29
User entered 'No (N)'	System	09 Sep 2020 04:14:29

FDA-CBER-2022-1614-0516235

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:19', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '29a3c543-5340-4066-8ece-5785a3ce6834'	System	09 Sep 2020 04:14:29
User entered 'No (N)'	System	09 Sep 2020 04:14:29

FDA-CBER-2022-1614-0516236

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:21', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '29a3c543-5340-4066-8ece-5785a3ce6834'	System	09 Sep 2020 04:14:29
User entered 'None (1)'	System	09 Sep 2020 04:14:29

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:24', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '29a3c543-5340-4066-8ece-5785a3ce6834'	System	09 Sep 2020 04:14:29
User entered '08 Sep 2020 21:14'	System	09 Sep 2020 04:14:29

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 20:57'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516239

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '09 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516240

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 2'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516241

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:27', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f401b90c-3cc6-40c8-bcd0-5e71c9598fbf'	System	10 Sep 2020 03:43:37
User entered 'None (1)'	System	10 Sep 2020 03:43:37

FDA-CBER-2022-1614-0516242

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:29', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f401b90c-3cc6-40c8-bcd0-5e71c9598fbf'	System	10 Sep 2020 03:43:37
User entered 'No (N)'	System	10 Sep 2020 03:43:37

FDA-CBER-2022-1614-0516243

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f401b90c-3cc6-40c8-bcd0-5e71c9598fbf'	System	10 Sep 2020 03:43:37
User entered 'No (N)'	System	10 Sep 2020 03:43:37

FDA-CBER-2022-1614-0516244

US3112221

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:10:42

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f401b90c-3cc6-40c8-bcd0-5e71c9598fbf'	System	10 Sep 2020 03:43:37
User entered 'None (1)'	System	10 Sep 2020 03:43:37

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:34', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f401b90c-3cc6-40c8-bcd0-5e71c9598fbf'	System	10 Sep 2020 03:43:37
User entered '09 Sep 2020 20:43'	System	10 Sep 2020 03:43:37

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516247

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516248

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 3'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516249

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:57:59', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bcd30fb8-f492-43a6-b80d-091338030edb'	System	11 Sep 2020 02:58:08
User entered 'None (1)'	System	11 Sep 2020 02:58:08

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:02', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bcd30fb8-f492-43a6-b80d-091338030edb'	System	11 Sep 2020 02:58:08
User entered 'No (N)'	System	11 Sep 2020 02:58:08

FDA-CBER-2022-1614-0516251

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:03', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bcd30fb8-f492-43a6-b80d-091338030edb'	System	11 Sep 2020 02:58:08
User entered 'No (N)'	System	11 Sep 2020 02:58:08

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bcd30fb8-f492-43a6-b80d-091338030edb'	System	11 Sep 2020 02:58:08
User entered 'None (1)'	System	11 Sep 2020 02:58:08

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:06', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bcd30fb8-f492-43a6-b80d-091338030edb'	System	11 Sep 2020 02:58:08
User entered '10 Sep 2020 19:58'	System	11 Sep 2020 02:58:08

FDA-CBER-2022-1614-0516254

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516255

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516256

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 4'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516257

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:05', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2f5537-9098-468e-9931-b6b8d9e3c248'	System	12 Sep 2020 07:00:16
User entered 'None (1)'	System	12 Sep 2020 07:00:16

FDA-CBER-2022-1614-0516258

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:07', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2f5537-9098-468e-9931-b6b8d9e3c248'	System	12 Sep 2020 07:00:16
User entered 'No (N)'	System	12 Sep 2020 07:00:16

FDA-CBER-2022-1614-0516259

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:09', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2f5537-9098-468e-9931-b6b8d9e3c248'	System	12 Sep 2020 07:00:16
User entered 'No (N)'	System	12 Sep 2020 07:00:16

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:10', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2f5537-9098-468e-9931-b6b8d9e3c248'	System	12 Sep 2020 07:00:16
User entered 'None (1)'	System	12 Sep 2020 07:00:16

FDA-CBER-2022-1614-0516261

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:13', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2f5537-9098-468e-9931-b6b8d9e3c248'	System	12 Sep 2020 07:00:16
User entered '12 Sep 2020 00:00'	System	12 Sep 2020 07:00:16

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516263

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516264

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 5'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516265

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3b4027b-82bb-4bb3-9dc9-14692fbfe88d'	System	12 Sep 2020 19:05:43
User entered 'None (1)'	System	12 Sep 2020 19:05:43

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:33', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3b4027b-82bb-4bb3-9dc9-14692fbfe88d'	System	12 Sep 2020 19:05:43
User entered 'No (N)'	System	12 Sep 2020 19:05:43

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3b4027b-82bb-4bb3-9dc9-14692fbfe88d'	System	12 Sep 2020 19:05:43
User entered 'No (N)'	System	12 Sep 2020 19:05:43

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:37', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3b4027b-82bb-4bb3-9dc9-14692fbfe88d'	System	12 Sep 2020 19:05:43
User entered 'None (1)'	System	12 Sep 2020 19:05:43

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:39', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3b4027b-82bb-4bb3-9dc9-14692fbfe88d'	System	12 Sep 2020 19:05:43
User entered '12 Sep 2020 12:05'	System	12 Sep 2020 19:05:43

FDA-CBER-2022-1614-0516270

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516271

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516272

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 6'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516273

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:44', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6c93f078-2a4f-436c-9952-4d7920927a26'	System	13 Sep 2020 19:01:50
User entered 'None (1)'	System	13 Sep 2020 19:01:50

FDA-CBER-2022-1614-0516274

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:46', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6c93f078-2a4f-436c-9952-4d7920927a26'	System	13 Sep 2020 19:01:50
User entered 'No (N)'	System	13 Sep 2020 19:01:50

FDA-CBER-2022-1614-0516275

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:47', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6c93f078-2a4f-436c-9952-4d7920927a26'	System	13 Sep 2020 19:01:50
User entered 'No (N)'	System	13 Sep 2020 19:01:50

FDA-CBER-2022-1614-0516276

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:49', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6c93f078-2a4f-436c-9952-4d7920927a26'	System	13 Sep 2020 19:01:50
User entered 'None (1)'	System	13 Sep 2020 19:01:50

FDA-CBER-2022-1614-0516277

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:51', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6c93f078-2a4f-436c-9952-4d7920927a26'	System	13 Sep 2020 19:01:50
User entered '13 Sep 2020 12:00'	System	13 Sep 2020 19:01:50

FDA-CBER-2022-1614-0516278

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516279

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516280

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 7'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516281

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:11', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '97d05fb6-eb27-4ae1-9546-31db7dda7dd2'	System	15 Sep 2020 11:39:22
User entered 'None (1)'	System	15 Sep 2020 11:39:22

FDA-CBER-2022-1614-0516282

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:13', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '97d05fb6-eb27-4ae1-9546-31db7dda7dd2'	System	15 Sep 2020 11:39:22
User entered 'No (N)'	System	15 Sep 2020 11:39:22

FDA-CBER-2022-1614-0516283

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:15', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '97d05fb6-eb27-4ae1-9546-31db7dda7dd2'	System	15 Sep 2020 11:39:22
User entered 'No (N)'	System	15 Sep 2020 11:39:22

FDA-CBER-2022-1614-0516284

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:17', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '97d05fb6-eb27-4ae1-9546-31db7dda7dd2'	System	15 Sep 2020 11:39:22
User entered 'None (1)'	System	15 Sep 2020 11:39:22

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:18', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '97d05fb6-eb27-4ae1-9546-31db7dda7dd2'	System	15 Sep 2020 11:39:22
User entered '15 Sep 2020 04:39'	System	15 Sep 2020 11:39:22

FDA-CBER-2022-1614-0516286

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516287

US3112221
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516288

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516289

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:17', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9e8bbea7-378e-4cab-ae63-64c7ea1dda76'	System	09 Sep 2020 00:50:38
User entered 'None (0)'	System	09 Sep 2020 00:50:38

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:19', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9e8bbea7-378e-4cab-ae63-64c7ea1dda76'	System	09 Sep 2020 00:50:38
User entered 'None (0)'	System	09 Sep 2020 00:50:38

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:20', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9e8bbea7-378e-4cab-ae63-64c7ea1dda76'	System	09 Sep 2020 00:50:38
User entered 'None (0)'	System	09 Sep 2020 00:50:38

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9e8bbea7-378e-4cab-ae63-64c7ea1dda76'	System	09 Sep 2020 00:50:38
User entered 'None (0)'	System	09 Sep 2020 00:50:38

FDA-CBER-2022-1614-0516293

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:23', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9e8bbea7-378e-4cab-ae63-64c7ea1dda76'	System	09 Sep 2020 00:50:38
User entered 'None (0)'	System	09 Sep 2020 00:50:38

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:25', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9e8bbea7-378e-4cab-ae63-64c7ea1dda76'	System	09 Sep 2020 00:50:38
User entered 'None (0)'	System	09 Sep 2020 00:50:38

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9e8bbea7-378e-4cab-ae63-64c7ea1dda76'	System	09 Sep 2020 00:50:38
User entered 'No (N)'	System	09 Sep 2020 00:50:38

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T17:50:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9e8bbea7-378e-4cab-ae63-64c7ea1dda76'	System	09 Sep 2020 00:50:38
User entered '08 Sep 2020 17:50'	System	09 Sep 2020 00:50:38

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 17:32'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516298

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 20:02'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516299

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516300

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:27', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3d601fb-1ae6-420a-a5f2-c57413915893'	System	09 Sep 2020 04:14:46
User entered 'None (0)'	System	09 Sep 2020 04:14:46

FDA-CBER-2022-1614-0516301

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:29', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3d601fb-1ae6-420a-a5f2-c57413915893'	System	09 Sep 2020 04:14:46
User entered 'None (0)'	System	09 Sep 2020 04:14:46

FDA-CBER-2022-1614-0516302

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3d601fb-1ae6-420a-a5f2-c57413915893'	System	09 Sep 2020 04:14:46
User entered 'None (0)'	System	09 Sep 2020 04:14:46

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3d601fb-1ae6-420a-a5f2-c57413915893'	System	09 Sep 2020 04:14:46
User entered 'None (0)'	System	09 Sep 2020 04:14:46

FDA-CBER-2022-1614-0516304

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:34', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3d601fb-1ae6-420a-a5f2-c57413915893'	System	09 Sep 2020 04:14:46
User entered 'None (0)'	System	09 Sep 2020 04:14:46

FDA-CBER-2022-1614-0516305

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:37', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3d601fb-1ae6-420a-a5f2-c57413915893'	System	09 Sep 2020 04:14:46
User entered 'None (0)'	System	09 Sep 2020 04:14:46

FDA-CBER-2022-1614-0516306

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:41', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3d601fb-1ae6-420a-a5f2-c57413915893'	System	09 Sep 2020 04:14:46
User entered 'No (N)'	System	09 Sep 2020 04:14:46

FDA-CBER-2022-1614-0516307

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-08T21:14:44', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f3d601fb-1ae6-420a-a5f2-c57413915893'	System	09 Sep 2020 04:14:46
User entered '08 Sep 2020 21:14'	System	09 Sep 2020 04:14:46

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '08 Sep 2020 20:57'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516309

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '09 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516310

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 2'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516311

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:37', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '039ccd52-4098-4c01-9c14-e6e527b796bc'	System	10 Sep 2020 03:43:51
User entered 'None (0)'	System	10 Sep 2020 03:43:51

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:38', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '039ccd52-4098-4c01-9c14-e6e527b796bc'	System	10 Sep 2020 03:43:51
User entered 'None (0)'	System	10 Sep 2020 03:43:51

FDA-CBER-2022-1614-0516313

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:40', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '039ccd52-4098-4c01-9c14-e6e527b796bc'	System	10 Sep 2020 03:43:51
User entered 'None (0)'	System	10 Sep 2020 03:43:51

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:41', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '039ccd52-4098-4c01-9c14-e6e527b796bc'	System	10 Sep 2020 03:43:51
User entered 'None (0)'	System	10 Sep 2020 03:43:51

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:42', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '039ccd52-4098-4c01-9c14-e6e527b796bc'	System	10 Sep 2020 03:43:51
User entered 'None (0)'	System	10 Sep 2020 03:43:51

FDA-CBER-2022-1614-0516316

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:44', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '039ccd52-4098-4c01-9c14-e6e527b796bc'	System	10 Sep 2020 03:43:51
User entered 'None (0)'	System	10 Sep 2020 03:43:51

FDA-CBER-2022-1614-0516317

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:47', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '039ccd52-4098-4c01-9c14-e6e527b796bc'	System	10 Sep 2020 03:43:51
User entered 'No (N)'	System	10 Sep 2020 03:43:51

FDA-CBER-2022-1614-0516318

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-09T20:43:49', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '039ccd52-4098-4c01-9c14-e6e527b796bc'	System	10 Sep 2020 03:43:51
User entered '09 Sep 2020 20:43'	System	10 Sep 2020 03:43:51

FDA-CBER-2022-1614-0516319

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516320

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516321

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 3'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516322

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:09', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '11262ee3-d52f-4a72-9210-6ee3872dd4bf'	System	11 Sep 2020 02:58:24
User entered 'None (0)'	System	11 Sep 2020 02:58:24

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:10', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '11262ee3-d52f-4a72-9210-6ee3872dd4bf'	System	11 Sep 2020 02:58:24
User entered 'None (0)'	System	11 Sep 2020 02:58:24

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:12', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '11262ee3-d52f-4a72-9210-6ee3872dd4bf'	System	11 Sep 2020 02:58:24
User entered 'None (0)'	System	11 Sep 2020 02:58:24

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:13', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '11262ee3-d52f-4a72-9210-6ee3872dd4bf'	System	11 Sep 2020 02:58:24
User entered 'None (0)'	System	11 Sep 2020 02:58:24

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:14', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '11262ee3-d52f-4a72-9210-6ee3872dd4bf'	System	11 Sep 2020 02:58:24
User entered 'None (0)'	System	11 Sep 2020 02:58:24

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:15', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '11262ee3-d52f-4a72-9210-6ee3872dd4bf'	System	11 Sep 2020 02:58:24
User entered 'None (0)'	System	11 Sep 2020 02:58:24

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:18', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '11262ee3-d52f-4a72-9210-6ee3872dd4bf'	System	11 Sep 2020 02:58:24
User entered 'No (N)'	System	11 Sep 2020 02:58:24

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-10T19:58:20', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '11262ee3-d52f-4a72-9210-6ee3872dd4bf'	System	11 Sep 2020 02:58:24
User entered '10 Sep 2020 19:58'	System	11 Sep 2020 02:58:24

FDA-CBER-2022-1614-0516330

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516331

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516332

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 4'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516333

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:18', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb5ca04e-7fc5-4fe5-af25-7af10eeb4787'	System	12 Sep 2020 07:00:34
User entered 'None (0)'	System	12 Sep 2020 07:00:34

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:20', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb5ca04e-7fc5-4fe5-af25-7af10eeb4787'	System	12 Sep 2020 07:00:34
User entered 'None (0)'	System	12 Sep 2020 07:00:34

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb5ca04e-7fc5-4fe5-af25-7af10eeb4787'	System	12 Sep 2020 07:00:34
User entered 'None (0)'	System	12 Sep 2020 07:00:34

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:24', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb5ca04e-7fc5-4fe5-af25-7af10eeb4787'	System	12 Sep 2020 07:00:34
User entered 'None (0)'	System	12 Sep 2020 07:00:34

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:25', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb5ca04e-7fc5-4fe5-af25-7af10eeb4787'	System	12 Sep 2020 07:00:34
User entered 'None (0)'	System	12 Sep 2020 07:00:34

FDA-CBER-2022-1614-0516338

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:27', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb5ca04e-7fc5-4fe5-af25-7af10eeb4787'	System	12 Sep 2020 07:00:34
User entered 'None (0)'	System	12 Sep 2020 07:00:34

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:29', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb5ca04e-7fc5-4fe5-af25-7af10eeb4787'	System	12 Sep 2020 07:00:34
User entered 'No (N)'	System	12 Sep 2020 07:00:34

FDA-CBER-2022-1614-0516340

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T00:00:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'bb5ca04e-7fc5-4fe5-af25-7af10eeb4787'	System	12 Sep 2020 07:00:34
User entered '12 Sep 2020 00:00'	System	12 Sep 2020 07:00:34

FDA-CBER-2022-1614-0516341

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516342

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516343

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 5'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516344

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:42', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '66f01a4b-38ca-4ad1-88dc-bac737f1fa3c'	System	12 Sep 2020 19:05:59
User entered 'None (0)'	System	12 Sep 2020 19:05:59

FDA-CBER-2022-1614-0516345

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:44', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '66f01a4b-38ca-4ad1-88dc-bac737f1fa3c'	System	12 Sep 2020 19:05:59
User entered 'None (0)'	System	12 Sep 2020 19:05:59

FDA-CBER-2022-1614-0516346

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:46', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '66f01a4b-38ca-4ad1-88dc-bac737f1fa3c'	System	12 Sep 2020 19:05:59
User entered 'None (0)'	System	12 Sep 2020 19:05:59

FDA-CBER-2022-1614-0516347

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:49', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '66f01a4b-38ca-4ad1-88dc-bac737f1fa3c'	System	12 Sep 2020 19:05:59
User entered 'None (0)'	System	12 Sep 2020 19:05:59

FDA-CBER-2022-1614-0516348

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:51', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '66f01a4b-38ca-4ad1-88dc-bac737f1fa3c'	System	12 Sep 2020 19:05:59
User entered 'None (0)'	System	12 Sep 2020 19:05:59

FDA-CBER-2022-1614-0516349

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:52', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '66f01a4b-38ca-4ad1-88dc-bac737f1fa3c'	System	12 Sep 2020 19:05:59
User entered 'None (0)'	System	12 Sep 2020 19:05:59

FDA-CBER-2022-1614-0516350

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:54', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '66f01a4b-38ca-4ad1-88dc-bac737f1fa3c'	System	12 Sep 2020 19:05:59
User entered 'No (N)'	System	12 Sep 2020 19:05:59

FDA-CBER-2022-1614-0516351

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-12T12:05:56', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '66f01a4b-38ca-4ad1-88dc-bac737f1fa3c'	System	12 Sep 2020 19:05:59
User entered '12 Sep 2020 12:05'	System	12 Sep 2020 19:05:59

FDA-CBER-2022-1614-0516352

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516353

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516354

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 6'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516355

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:57', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '74bf5ab7-59fe-4f04-a3c7-7a56405bada6'	System	13 Sep 2020 19:02:08
User entered 'None (0)'	System	13 Sep 2020 19:02:08

FDA-CBER-2022-1614-0516356

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:58', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '74bf5ab7-59fe-4f04-a3c7-7a56405bada6'	System	13 Sep 2020 19:02:08
User entered 'None (0)'	System	13 Sep 2020 19:02:08

FDA-CBER-2022-1614-0516357

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:00:59', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '74bf5ab7-59fe-4f04-a3c7-7a56405bada6'	System	13 Sep 2020 19:02:08
User entered 'None (0)'	System	13 Sep 2020 19:02:08

FDA-CBER-2022-1614-0516358

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:01:01', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '74bf5ab7-59fe-4f04-a3c7-7a56405bada6'	System	13 Sep 2020 19:02:08
User entered 'None (0)'	System	13 Sep 2020 19:02:08

FDA-CBER-2022-1614-0516359

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:01:02', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '74bf5ab7-59fe-4f04-a3c7-7a56405bada6'	System	13 Sep 2020 19:02:08
User entered 'None (0)'	System	13 Sep 2020 19:02:08

FDA-CBER-2022-1614-0516360

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:01:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '74bf5ab7-59fe-4f04-a3c7-7a56405bada6'	System	13 Sep 2020 19:02:08
User entered 'None (0)'	System	13 Sep 2020 19:02:08

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:01:06', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '74bf5ab7-59fe-4f04-a3c7-7a56405bada6'	System	13 Sep 2020 19:02:08
User entered 'No (N)'	System	13 Sep 2020 19:02:08

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-13T12:01:08', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '74bf5ab7-59fe-4f04-a3c7-7a56405bada6'	System	13 Sep 2020 19:02:08
User entered '13 Sep 2020 12:01'	System	13 Sep 2020 19:02:08

FDA-CBER-2022-1614-0516363

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516364

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516365

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	09 Sep 2020 00:28:59
User entered 'Day 7'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516366

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2bdff7-5ea8-4957-b5ad-69a2ae7e4a27'	System	15 Sep 2020 11:39:46
User entered 'None (0)'	System	15 Sep 2020 11:39:46

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:25', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2bdff7-5ea8-4957-b5ad-69a2ae7e4a27'	System	15 Sep 2020 11:39:46
User entered 'None (0)'	System	15 Sep 2020 11:39:46

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:28', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2bdff7-5ea8-4957-b5ad-69a2ae7e4a27'	System	15 Sep 2020 11:39:46
User entered 'None (0)'	System	15 Sep 2020 11:39:46

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:30', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2bdff7-5ea8-4957-b5ad-69a2ae7e4a27'	System	15 Sep 2020 11:39:46
User entered 'None (0)'	System	15 Sep 2020 11:39:46

FDA-CBER-2022-1614-0516370

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2bdff7-5ea8-4957-b5ad-69a2ae7e4a27'	System	15 Sep 2020 11:39:46
User entered 'None (0)'	System	15 Sep 2020 11:39:46

FDA-CBER-2022-1614-0516371

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2bdff7-5ea8-4957-b5ad-69a2ae7e4a27'	System	15 Sep 2020 11:39:46
User entered 'None (0)'	System	15 Sep 2020 11:39:46

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:40', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2bdff7-5ea8-4957-b5ad-69a2ae7e4a27'	System	15 Sep 2020 11:39:46
User entered 'Yes (Y)'	System	15 Sep 2020 11:39:46

FDA-CBER-2022-1614-0516373

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-09-15T04:39:42', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '6f2bdff7-5ea8-4957-b5ad-69a2ae7e4a27'	System	15 Sep 2020 11:39:46
User entered '15 Sep 2020 04:39'	System	15 Sep 2020 11:39:46

FDA-CBER-2022-1614-0516374

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516375

US3112221
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:10:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 00:28:59

FDA-CBER-2022-1614-0516376

US3112221
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:51

FDA-CBER-2022-1614-0516377

US3112221
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:51

FDA-CBER-2022-1614-0516378

US3112221
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:51

FDA-CBER-2022-1614-0516379

US3112221
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:51

FDA-CBER-2022-1614-0516380

US3112221
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:16:59

FDA-CBER-2022-1614-0516381

US3112221
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered '1'	System	22 Sep 2020 23:16:59

FDA-CBER-2022-1614-0516382

US3112221
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:18:50

FDA-CBER-2022-1614-0516383

US3112221
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '22 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:18:50

FDA-CBER-2022-1614-0516384

US3112221
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:18:50

FDA-CBER-2022-1614-0516385

US3112221
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:18:50

FDA-CBER-2022-1614-0516386

US3112221
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	22 Sep 2020 23:18:58

FDA-CBER-2022-1614-0516387

US3112221
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered '1'	System	22 Sep 2020 23:18:58

FDA-CBER-2022-1614-0516388

US3112221
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:21:59

FDA-CBER-2022-1614-0516389

US3112221
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '29 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:21:59

FDA-CBER-2022-1614-0516390

US3112221
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:21:59

FDA-CBER-2022-1614-0516391

US3112221
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:21:59

FDA-CBER-2022-1614-0516392

US3112221
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	29 Sep 2020 18:22:09

FDA-CBER-2022-1614-0516393

US3112221
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered '1'	System	29 Sep 2020 18:22:09

FDA-CBER-2022-1614-0516394

US3112221
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:26:54

FDA-CBER-2022-1614-0516395

US3112221
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '6 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:26:54

FDA-CBER-2022-1614-0516396

US3112221
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:26:54

FDA-CBER-2022-1614-0516397

US3112221
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered 'VISIT3'	System	13 Oct 2020 16:26:54

FDA-CBER-2022-1614-0516398

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516399

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '6 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516400

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '14:06'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516401

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered '6 Oct 2020 14:06'	System	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516402

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '98.7' F	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516403

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516404

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516405

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '88'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516406

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered 'bpm'	System	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516407

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '16'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516408

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered 'breaths/min'	System	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516409

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '128'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516410

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered 'mmHg'	System	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516411

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '97'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516412

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered 'mmHg'	System	13 Oct 2020 16:28:08

FDA-CBER-2022-1614-0516413

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50

FDA-CBER-2022-1614-0516414

US3112221
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50

FDA-CBER-2022-1614-0516415

US3112221
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:26

FDA-CBER-2022-1614-0516416

US3112221
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:28:26

FDA-CBER-2022-1614-0516417

US3112221
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:29:09

FDA-CBER-2022-1614-0516418

US3112221
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '6 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:29:09

FDA-CBER-2022-1614-0516419

US3112221
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '14:15'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:29:09

FDA-CBER-2022-1614-0516420

US3112221
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered '6 Oct 2020 14:15'	System	13 Oct 2020 16:29:09

FDA-CBER-2022-1614-0516421

US3112221
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:29:15

FDA-CBER-2022-1614-0516422

US3112221
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:45:50
User entered '1'	System	13 Oct 2020 16:29:15

FDA-CBER-2022-1614-0516423

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 64'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516424

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-12T13:09:26', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'feb619a4-9eed-4b50-a92d-3c0d3000f292'	System	12 Oct 2020 20:09:55
User entered 'No (N)'	System	12 Oct 2020 20:09:55

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-12T13:09:36', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'feb619a4-9eed-4b50-a92d-3c0d3000f292'	System	12 Oct 2020 20:09:55
User entered 'Yes (Y)'	System	12 Oct 2020 20:09:55

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Please 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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-12T13:09:41', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'feb619a4-9eed-4b50-a92d-3c0d3000f292'	System	12 Oct 2020 20:09:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Oct 2020 20:09:55

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-12T13:09:44', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'feb619a4-9eed-4b50-a92d-3c0d3000f292'	System	12 Oct 2020 20:09:55
User entered '12 Oct 2020 13:09:44'	System	12 Oct 2020 20:09:55

FDA-CBER-2022-1614-0516428

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '12 Oct 2020 00:01'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516429

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '16 Oct 2020 23:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516430

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 71'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516431

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-19T00:12:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'e68d17b0-2619-4a6a-86d3-e1033573addb'	System	19 Oct 2020 07:12:40
User entered 'No (N)'	System	19 Oct 2020 07:12:40

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-19T00:12:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'e68d17b0-2619-4a6a-86d3-e1033573addb'	System	19 Oct 2020 07:12:40
User entered 'No (N)'	System	19 Oct 2020 07:12:40

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-19T00:12:38', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'e68d17b0-2619-4a6a-86d3-e1033573addb'	System	19 Oct 2020 07:12:40
User entered '19 Oct 2020 00:12:38'	System	19 Oct 2020 07:12:40

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '19 Oct 2020 00:01'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516435

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '23 Oct 2020 23:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516436

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 78'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516437

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-26T01:14:57', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'ca0f1f06-b75a-4658-80db-761404ac43ae'	System	26 Oct 2020 08:15:14
User entered 'No (N)'	System	26 Oct 2020 08:15:14

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-26T01:15:07', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'ca0f1f06-b75a-4658-80db-761404ac43ae'	System	26 Oct 2020 08:15:14
User entered 'No (N)'	System	26 Oct 2020 08:15:14

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-10-26T01:15:11', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'ca0f1f06-b75a-4658-80db-761404ac43ae'	System	26 Oct 2020 08:15:14
User entered '26 Oct 2020 01:15:11'	System	26 Oct 2020 08:15:14

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '26 Oct 2020 00:01'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516441

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '30 Oct 2020 23:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516442

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 92'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516443

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-09T03:56:13', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '280a3ab0-9bfc-4f4a-bd0b-a0dc652d5830'	System	09 Nov 2020 11:56:20
User entered 'No (N)'	System	09 Nov 2020 11:56:20

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-09T03:56:15', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '280a3ab0-9bfc-4f4a-bd0b-a0dc652d5830'	System	09 Nov 2020 11:56:20
User entered 'No (N)'	System	09 Nov 2020 11:56:20

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-09T03:56:18', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '280a3ab0-9bfc-4f4a-bd0b-a0dc652d5830'	System	09 Nov 2020 11:56:20
User entered '09 Nov 2020 03:56:18'	System	09 Nov 2020 11:56:20

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '09 Nov 2020 00:01'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516447

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:40
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '13 Nov 2020 23:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516448

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12
Data entry locked.	System	13 Aug 2020 00:13:23
User entered 'Day 99'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516449

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516454

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516455

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516456

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516457

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516458

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516459

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516460

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516461

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516462

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516464

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516465

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516466

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516467

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516468

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516469

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516470

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

US3112221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516474

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '16 Nov 2020 00:01'	System	13 Aug 2020 00:13:23

US3112221
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:38:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:12
Data entry locked.	System	13 Aug 2020 00:13:23
User entered '20 Nov 2020 23:59'	System	13 Aug 2020 00:13:23

FDA-CBER-2022-1614-0516476

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516477

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-22T18:07:20', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'df8acec1-3aa0-4f9e-9479-73b3b48146ee'	System	23 Nov 2020 02:07:29
User entered 'No (N)'	System	23 Nov 2020 02:07:29

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-22T18:07:22', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'df8acec1-3aa0-4f9e-9479-73b3b48146ee'	System	23 Nov 2020 02:07:29
User entered 'No (N)'	System	23 Nov 2020 02:07:29

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-22T18:07:25', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'df8acec1-3aa0-4f9e-9479-73b3b48146ee'	System	23 Nov 2020 02:07:29
User entered '22 Nov 2020 18:07:25'	System	23 Nov 2020 02:07:29

FDA-CBER-2022-1614-0516480

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516481

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516482

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516483

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-27T01:48:29', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '4f412675-131c-4bcd-a7ef-7ba594e38f7b'	System	27 Nov 2020 09:48:37
User entered 'No (N)'	System	27 Nov 2020 09:48:37

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-27T01:48:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '4f412675-131c-4bcd-a7ef-7ba594e38f7b'	System	27 Nov 2020 09:48:37
User entered 'No (N)'	System	27 Nov 2020 09:48:37

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-11-27T01:48:34', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '4f412675-131c-4bcd-a7ef-7ba594e38f7b'	System	27 Nov 2020 09:48:37
User entered '27 Nov 2020 01:48:34'	System	27 Nov 2020 09:48:37

FDA-CBER-2022-1614-0516486

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516487

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516488

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516489

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:14:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered 'Yes (Y)'	System	06 Dec 2020 20:15:49

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:14:40', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered 'No (N)'	System	06 Dec 2020 20:15:49

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:14:45', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered 'Yes (Y)'	System	06 Dec 2020 20:15:49

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '1'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516493

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '1'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516494

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '1'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516495

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516496

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516497

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '1'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516498

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516499

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '1'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516500

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '1'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516501

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516503

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516504

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516505

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516506

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516507

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '1'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516508

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:04', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '0'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516509

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Please 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:27', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 20:15:49

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered 'Yes (Y)'	System	06 Dec 2020 20:15:49

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Please 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:36', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 20:15:49

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-06T12:15:40', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '42e364be-5788-4ff6-99b9-597fec793a50'	System	06 Dec 2020 20:15:49
User entered '06 Dec 2020 12:15:40'	System	06 Dec 2020 20:15:49

FDA-CBER-2022-1614-0516513

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516514

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516515

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516516

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-11T02:57:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '49ad4b47-dc24-4ee8-a7a2-6888d4e12caf'	System	11 Dec 2020 10:57:39
User entered 'No (N)'	System	11 Dec 2020 10:57:39

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-11T02:57:33', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '49ad4b47-dc24-4ee8-a7a2-6888d4e12caf'	System	11 Dec 2020 10:57:39
User entered 'No (N)'	System	11 Dec 2020 10:57:39

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-11T02:57:37', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '49ad4b47-dc24-4ee8-a7a2-6888d4e12caf'	System	11 Dec 2020 10:57:39
User entered '11 Dec 2020 02:57:37'	System	11 Dec 2020 10:57:39

FDA-CBER-2022-1614-0516519

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516520

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516521

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516522

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-18T03:00:03', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3885742a-5f64-445a-b1d1-9c224bdb3c14'	System	18 Dec 2020 11:00:20
User entered 'No (N)'	System	18 Dec 2020 11:00:20

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-18T03:00:12', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3885742a-5f64-445a-b1d1-9c224bdb3c14'	System	18 Dec 2020 11:00:20
User entered 'No (N)'	System	18 Dec 2020 11:00:20

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-18T03:00:16', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '3885742a-5f64-445a-b1d1-9c224bdb3c14'	System	18 Dec 2020 11:00:20
User entered '18 Dec 2020 03:00:16'	System	18 Dec 2020 11:00:20

FDA-CBER-2022-1614-0516525

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516526

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516527

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516528

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-25T02:37:11', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9dc125ac-e9e1-4ac1-9ee0-1abe7a107ca9'	System	25 Dec 2020 10:37:23
User entered 'No (N)'	System	25 Dec 2020 10:37:23

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-25T02:37:17', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9dc125ac-e9e1-4ac1-9ee0-1abe7a107ca9'	System	25 Dec 2020 10:37:23
User entered 'No (N)'	System	25 Dec 2020 10:37:23

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2020-12-25T02:37:21', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '9dc125ac-e9e1-4ac1-9ee0-1abe7a107ca9'	System	25 Dec 2020 10:37:23
User entered '25 Dec 2020 02:37:21'	System	25 Dec 2020 10:37:23

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516532

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516533

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516534

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-01T05:06:49', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '73b37083-d662-4085-a23a-58eb9865e913'	System	01 Jan 2021 13:06:57
User entered 'No (N)'	System	01 Jan 2021 13:06:57

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-01T05:06:51', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '73b37083-d662-4085-a23a-58eb9865e913'	System	01 Jan 2021 13:06:57
User entered 'No (N)'	System	01 Jan 2021 13:06:57

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-01T05:06:55', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '73b37083-d662-4085-a23a-58eb9865e913'	System	01 Jan 2021 13:06:57
User entered '01 Jan 2021 05:06:55'	System	01 Jan 2021 13:06:57

FDA-CBER-2022-1614-0516537

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516538

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516539

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516540

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-08T02:25:33', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'af54d6cb-dd29-4878-a0c4-54c55680dcd7'	System	08 Jan 2021 10:25:43
User entered 'No (N)'	System	08 Jan 2021 10:25:43

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-08T02:25:35', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'af54d6cb-dd29-4878-a0c4-54c55680dcd7'	System	08 Jan 2021 10:25:43
User entered 'No (N)'	System	08 Jan 2021 10:25:43

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-08T02:25:39', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'af54d6cb-dd29-4878-a0c4-54c55680dcd7'	System	08 Jan 2021 10:25:43
User entered '08 Jan 2021 02:25:39'	System	08 Jan 2021 10:25:43

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516544

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516545

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516546

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-15T01:11:25', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '4b16c463-8a1e-4aa0-8c22-da49c294e048'	System	15 Jan 2021 09:11:36
User entered 'No (N)'	System	15 Jan 2021 09:11:36

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-15T01:11:28', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '4b16c463-8a1e-4aa0-8c22-da49c294e048'	System	15 Jan 2021 09:11:36
User entered 'No (N)'	System	15 Jan 2021 09:11:36

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-15T01:11:31', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '4b16c463-8a1e-4aa0-8c22-da49c294e048'	System	15 Jan 2021 09:11:36
User entered '15 Jan 2021 01:11:31'	System	15 Jan 2021 09:11:36

FDA-CBER-2022-1614-0516549

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516550

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516551

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516552

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-22T04:59:58', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1001354f-04d9-4917-b268-433aa3efa4bb'	System	22 Jan 2021 13:00:24
User entered 'Yes (Y)'	System	22 Jan 2021 13:00:24

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-22T05:00:01', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1001354f-04d9-4917-b268-433aa3efa4bb'	System	22 Jan 2021 13:00:24
User entered 'No (N)'	System	22 Jan 2021 13:00:24

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-22T05:00:05', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1001354f-04d9-4917-b268-433aa3efa4bb'	System	22 Jan 2021 13:00:24
User entered 'No (N)'	System	22 Jan 2021 13:00:24

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-22T05:00:15', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1001354f-04d9-4917-b268-433aa3efa4bb'	System	22 Jan 2021 13:00:24
User entered 'No (N)'	System	22 Jan 2021 13:00:24

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-22T05:00:21', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: '1001354f-04d9-4917-b268-433aa3efa4bb'	System	22 Jan 2021 13:00:24
User entered '22 Jan 2021 05:00:21'	System	22 Jan 2021 13:00:24

FDA-CBER-2022-1614-0516557

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516558

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516559

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516560

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-29T03:35:17', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f7fe7508-583a-44bd-ab70-156f09c8064a'	System	29 Jan 2021 11:35:46
User entered 'Yes (Y)'	System	29 Jan 2021 11:35:46

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-29T03:35:23', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f7fe7508-583a-44bd-ab70-156f09c8064a'	System	29 Jan 2021 11:35:46
User entered 'No (N)'	System	29 Jan 2021 11:35:46

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-29T03:35:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f7fe7508-583a-44bd-ab70-156f09c8064a'	System	29 Jan 2021 11:35:46
User entered 'No (N)'	System	29 Jan 2021 11:35:46

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-29T03:35:37', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f7fe7508-583a-44bd-ab70-156f09c8064a'	System	29 Jan 2021 11:35:46
User entered 'No (N)'	System	29 Jan 2021 11:35:46

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-01-29T03:35:43', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'f7fe7508-583a-44bd-ab70-156f09c8064a'	System	29 Jan 2021 11:35:46
User entered '29 Jan 2021 03:35:43'	System	29 Jan 2021 11:35:46

FDA-CBER-2022-1614-0516565

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516566

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516567

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516568

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-02-05T00:58:32', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'e3804270-3e39-489a-8939-6e988b68a051'	System	05 Feb 2021 08:58:41
User entered 'No (N)'	System	05 Feb 2021 08:58:41

US3112221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:42

Have you been exposed to someone with 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)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-02-05T00:58:36', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'e3804270-3e39-489a-8939-6e988b68a051'	System	05 Feb 2021 08:58:41
User entered 'No (N)'	System	05 Feb 2021 08:58:41

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-02-05T00:58:39', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'e3804270-3e39-489a-8939-6e988b68a051'	System	05 Feb 2021 08:58:41
User entered '05 Feb 2021 00:58:39'	System	05 Feb 2021 08:58:41

FDA-CBER-2022-1614-0516571

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516572

US3112221
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:10:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:12
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:37:12

FDA-CBER-2022-1614-0516573

US3112221

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:10:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-03-17T01:57:13-07:00', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'b7143557-1fda-4d38-b9e8-65a1c6ee349c'	System	17 Mar 2021 08:57:25
User entered 'No (N)'	System	17 Mar 2021 08:57:25

US3112221
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 09 Jun 2021 15:10:42
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EC9CD816-1566-472D-A904-E55745742CAA)', Time: '2021-03-17T01:57:22-07:00', User OID: 'PatientReportedOutcome (US3112221)', ODM File OID: 'b7143557-1fda-4d38-b9e8-65a1c6ee349c'	System	17 Mar 2021 08:57:25
User entered '17 Mar 2021 01:57:22'	System	17 Mar 2021 08:57:25

US3112221
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:31:08
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	02 Nov 2020 22:15:46

FDA-CBER-2022-1614-0516576

US3112221
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:31:08
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '02 Nov 2020'	Matthew Musikanth (b) (4)	02 Nov 2020 22:15:46

FDA-CBER-2022-1614-0516577

US3112221
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:31:08
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	02 Nov 2020 22:15:46

FDA-CBER-2022-1614-0516578

US3112221
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:31:08
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	02 Nov 2020 22:15:46

US3112221
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:31:08
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	02 Nov 2020 22:15:49

FDA-CBER-2022-1614-0516580

US3112221
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:31:08
User entered '1'	System	02 Nov 2020 22:15:49

FDA-CBER-2022-1614-0516581

US3112221
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:35

US3112221
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:35

US3112221
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:35

US3112221
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'not conducted due to illness visits'	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:35

FDA-CBER-2022-1614-0516585

US3112221
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:48

FDA-CBER-2022-1614-0516586

US3112221
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User entered '1'	System	05 Jan 2021 18:52:48

FDA-CBER-2022-1614-0516587

US3112221
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:59

US3112221
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '5 Jan 2021'	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:59

US3112221
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:59

US3112221
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:52:59

US3112221
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	05 Jan 2021 18:53:05

FDA-CBER-2022-1614-0516592

US3112221
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User entered '1'	System	05 Jan 2021 18:53:05

US3112221
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	16 Feb 2021 23:32:48

US3112221
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '03 Feb 2021'	Matthew Musikanth (b) (4)	16 Feb 2021 23:32:48

FDA-CBER-2022-1614-0516595

US3112221
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	16 Feb 2021 23:32:48

FDA-CBER-2022-1614-0516596

US3112221
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:10:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	16 Feb 2021 23:32:48

US3112221
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Feb 2021 23:32:55

US3112221
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:10:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:43:53
User entered empty.	System	16 Feb 2021 23:32:55

FDA-CBER-2022-1614-0516599

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:10:42
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:49
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:08:59

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:10:42
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:49
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '08:33'	Matthew Musikanth (b) (4)	08 Dec 2020 00:08:59

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:10:42
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:49
User entered '07 Dec 2020 08:33'	System	08 Dec 2020 00:08:59

FDA-CBER-2022-1614-0516602

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:10:42
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:49
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Safety Call (Safety Call)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:08:59

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:10:42
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:49
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:08:59

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 1 (Day 1)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516605

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '30 Nov 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516609

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516611

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516613

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516615

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516617

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516622

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516623

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516624

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (1)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:13:30

FDA-CBER-2022-1614-0516626

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 2 (Day 2)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516627

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '01 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516628

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516630

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516631

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516632

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516633

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516634

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516635

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516637

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516639

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516640

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516643

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516644

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516645

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516646

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516647

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (2)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516649

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '02 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516650

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516652

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516653

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516654

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516655

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516656

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516657

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516659

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516661

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516662

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516663

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516664

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516666

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516667

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516668

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516669

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (3)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 4 (Day 4)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516671

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '03 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516672

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516673

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516674

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516675

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516676

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516678

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516679

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516683

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516684

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516689

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516691

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (4)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516693

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '04 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516694

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516696

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516697

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516698

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516699

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516702

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516703

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516705

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516706

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516711

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516712

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516713

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (5)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 6 (Day 6)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516715

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '05 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516716

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516718

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516719

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516723

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516724

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516725

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516728

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516732

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516733

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516734

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (6)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '06 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516738

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516740

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516741

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516742

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516743

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516755

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (7)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 8 (Day 8)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516759

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516760

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '98'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516763

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '97.8' F	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516764

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516765

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516766

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516769

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516771

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516772

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516773

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516774

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516776

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516777

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516778

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

FDA-CBER-2022-1614-0516779

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (8)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:19:42

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User closed query 'Per ETRTR: As per lab report dated 11-Dec-2020, the symptom log is required to be maintained up to 10-Dec-2020. Please update 09-Dec-2020 and 10-Dec-2020 log. Thank You!' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:48:08
Query 'Per ETRTR: As per lab report dated 11-Dec-2020, the symptom log is required to be maintained up to 10-Dec-2020. Please update 09-Dec-2020 and 10-Dec-2020 log. Thank You!' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	23 Apr 2021 14:53:40
User opened query 'Per ETRTR: As per lab report dated 11-Dec-2020, the symptom log is required to be maintained up to 10-Dec-2020. Please update 09-Dec-2020 and 10-Dec-2020 log. Thank You!' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 12:15:17
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516781

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '08 Dec 2020'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516782

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '99'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516784

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516785

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '97' F	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516786

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516788

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516791

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516793

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516794

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516797

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

FDA-CBER-2022-1614-0516799

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (9)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'None (None)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:32:29

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'Day 10 (Day 10)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516803

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '09 Dec 2020'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516804

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '0'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '98'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516807

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '96.8' F	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516819

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (10)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516824

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Symptom Day

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'Day 11 (Day 11)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516825

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '10 Dec 2020'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Assessment Not Done

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '0'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516827

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '99'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
O2 Saturation Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User entered '%'	System	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516829

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '97.1' F	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516832

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Shortness of Breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516834

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516836

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516838

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
New Loss of Taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516839

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
New Loss of Smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

FDA-CBER-2022-1614-0516843

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Symptom Log (11)
Generated On: 09 Jun 2021 15:10:42
Sore Throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'None (None)'	Matthew Musikanth (b) (4)	23 Apr 2021 14:52:34

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
Date of Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

FDA-CBER-2022-1614-0516847

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

FDA-CBER-2022-1614-0516848

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 03:33:24
Query 'Data is required. Please complete.' answered with 'pending' (Site from System).	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:21
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 00:09:14
User entered empty.	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
Date of Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

FDA-CBER-2022-1614-0516850

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

FDA-CBER-2022-1614-0516851

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

FDA-CBER-2022-1614-0516852

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42

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)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

FDA-CBER-2022-1614-0516853

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
Lab/ Institution Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

FDA-CBER-2022-1614-0516854

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
CLIA Certified?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	08 Dec 2020 00:09:14

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: COVID Diagnostic Test
Generated On: 09 Jun 2021 15:10:42
COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:34
User entered '0'	System	15 Dec 2020 00:58:28

FDA-CBER-2022-1614-0516856

US3112221
Folder: Covid-19 Assessment 07 Dec 2020
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 15:10:42
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:21:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Mar 2021 23:19:44

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 15:10:42
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516858

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 15:10:42
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516859

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (1)
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 08:43:01
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'has been updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	17 Dec 2020 23:16:25
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 05:04:35
User entered '09 Dec 2020'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516860

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 15:10:42
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516861

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 15:10:42
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User closed query 'Per CDM: Date of collection recorded as 11DEC2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:18:11
Query 'Per CDM: Date of collection recorded as 11DEC2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 23:29:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 23:28:58
User opened query 'Per CDM: Date of collection recorded as 11DEC2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:25:42
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (2)
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '11 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	17 Dec 2020 23:15:56
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516863

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 15:10:42
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516864

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 15:10:42
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516865

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (3)
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516866

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 15:10:42
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516867

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 15:10:42
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516868

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (4)
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 15:10:42
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516870

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 15:10:42
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516871

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (5)
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516872

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 15:10:42
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516873

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 15:10:42
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516874

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (6)
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 15:10:42
Visit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516876

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 15:10:42
Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

FDA-CBER-2022-1614-0516877

US3112221
Folder: Illness Visit (1)
Form: Saliva Collection (7)
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:59:15

US3112221
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:20:14

FDA-CBER-2022-1614-0516879

US3112221
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:20:14

FDA-CBER-2022-1614-0516880

US3112221
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:20:14

US3112221
Folder: Illness Visit Day 1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'SICKD1'	System	08 Dec 2020 00:20:14

FDA-CBER-2022-1614-0516882

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516883

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516884

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '10:22'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516885

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered '07 Dec 2020 10:22'	System	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516886

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00
DataPoint set to visible.	System	08 Dec 2020 00:20:14

FDA-CBER-2022-1614-0516887

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00
DataPoint set to visible.	System	08 Dec 2020 00:20:14

FDA-CBER-2022-1614-0516888

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '97.8' F	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516889

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516890

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516891

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '68'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516892

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'bpm'	System	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516893

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '14'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516894

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'breaths/min'	System	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516895

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '122'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516896

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'mmHg'	System	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516897

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '76'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516898

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'mmHg'	System	08 Dec 2020 00:21:00

FDA-CBER-2022-1614-0516899

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24

FDA-CBER-2022-1614-0516900

US3112221
Folder: Illness Visit Day 1 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24

FDA-CBER-2022-1614-0516901

US3112221
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:07

FDA-CBER-2022-1614-0516902

US3112221
Folder: Illness Visit Day 1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:07

FDA-CBER-2022-1614-0516903

US3112221
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 15:10:42
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:18

US3112221
Folder: Illness Visit Day 1 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	08 Dec 2020 00:21:18

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:43

FDA-CBER-2022-1614-0516906

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:43

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:43

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'SICKD28'	System	15 Dec 2020 00:58:43

FDA-CBER-2022-1614-0516909

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516910

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516911

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516912

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered empty.	System	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516913

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516916

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered empty.	System	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516918

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered empty.	System	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516920

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered empty.	System	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516922

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:49

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered empty.	System	15 Dec 2020 00:58:49

FDA-CBER-2022-1614-0516924

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24

FDA-CBER-2022-1614-0516925

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:10:42
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24

FDA-CBER-2022-1614-0516926

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:54

FDA-CBER-2022-1614-0516927

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:10:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:54

FDA-CBER-2022-1614-0516928

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 15:10:42
Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'NA (COVID-19 Negative) (NA)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:59

FDA-CBER-2022-1614-0516929

US3112221
Folder: Convalescence Visit Day 28 (1)
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 09 Jun 2021 15:10:42
Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:58:59

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:05

FDA-CBER-2022-1614-0516931

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '9 Feb 2021'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:05

FDA-CBER-2022-1614-0516932

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:05

FDA-CBER-2022-1614-0516933

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:10:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 22:46:05

FDA-CBER-2022-1614-0516934

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '6 Jan 2021'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516935

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Mar 2021 16:34:06
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:26:25

FDA-CBER-2022-1614-0516936

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516937

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Mar 2021 16:34:06
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:26:25

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '9 Feb 2021'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516939

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516940

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516941

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516942

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516943

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User entered '1'	System	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516944

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:10:42
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User entered empty.	System	09 Feb 2021 22:46:57

FDA-CBER-2022-1614-0516945

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:47:05

FDA-CBER-2022-1614-0516946

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '9 Feb 2021'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:47:05

FDA-CBER-2022-1614-0516947

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '10:15'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:47:05

FDA-CBER-2022-1614-0516948

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:10:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User entered '9 Feb 2021 10:15'	System	09 Feb 2021 22:47:05

FDA-CBER-2022-1614-0516949

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:10:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, “please confirm swab tube is not empty as subject declined np swab”; however, swab sample for this subject is present in Preclarus with accession number # 1F657375259, collection date as 09-FEB-2021. Kindly review & confirm if swab sample was collected or not, if not please confirm the correct subject ID to which this accession number belongs to be updated in EDC and Preclarus portal as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:17:06
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, “please confirm swab tube is not empty as subject declined np swab”; however, swab sample for this subject is present in Preclarus with accession number # 1F657375259, collection date as 09-FEB-2021. Kindly review & confirm if swab sample was collected or not, if not please confirm the correct subject ID to which this accession number belongs to be updated in EDC and Preclarus portal as appropriate, else clarify. ' answered with 'NP not collec ted subject declined' (Site from DM).	Brenda Grande (b) (4) (b) (4)	05 Apr 2021 21:26:24
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, “please confirm swab tube is not empty as subject declined np swab”; however, swab sample for this subject is present in Preclarus with accession number # 1F657375259, collection date as 09-FEB-2021. Kindly review & confirm if swab sample was collected or not, if not please confirm the correct subject ID to which this accession number belongs to be updated in EDC and Preclarus portal as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 03:53:42

US3112221

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:10:42

Was the sample collected?

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 09-FEB-2021 for the Participant Decision Visit / OL-D1, however, Was the sample collected? is No. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 03:53:42
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 09-FEB-2021 for the Participant Decision Visit / OL-D1, however, Was the sample collected? is No. Please clarify and update as appropriate.' answered with 'please confirm the tube is not empty as subject declined swab ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	25 Mar 2021 15:41:36
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, there is a Swab sample collected on 09-FEB-2021 for the Participant Decision Visit / OL-D1, however, Was the sample collected? is No. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 10:27:39
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:47:22

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:10:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:47:22

FDA-CBER-2022-1614-0516952

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:10:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Natalie Moy (b) (4) (b) (4)	09 Feb 2021 22:47:22

FDA-CBER-2022-1614-0516953

US3112221
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:10:42
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:17:58
User entered empty.	System	09 Feb 2021 22:47:22

FDA-CBER-2022-1614-0516954

US3112221
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:10:42
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:19
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:45:56

FDA-CBER-2022-1614-0516955

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 00:48:44
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 00:48:44
Data point term sent to Coder	System	15 Dec 2020 00:47:15
User entered 'Viral Syndrome'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516957

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516958

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516959

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '30 Nov 2020'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516961

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User entered empty.	System	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516963

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 00:46:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 00:46:48
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:48
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Dec 2020 00:46:36
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516964

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '08 Dec 2020'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516965

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User entered empty.	System	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516967

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516968

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516971

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516972

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516973

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516974

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516976

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516979

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516980

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516981

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516982

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '1'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516984

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516985

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516986

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516987

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:46:36

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User entered '0'	System	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516989

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28
User entered '1'	System	15 Dec 2020 00:46:36

FDA-CBER-2022-1614-0516990

US3112221
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:10:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:15:28

FDA-CBER-2022-1614-0516991

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:23
User entered 'USA-US062-2021-mRNA-1273-P301000010'	System	05 Feb 2021 13:14:19
User entered 'New'	(b) (4), (b) (6)	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0516992

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colorectal cancer metastatic, LLT: Colorectal cancer metastatic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:55:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:55:54
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:10:14
Data point term sent to Coder	System	24 Feb 2021 19:37:46
User entered 'METASTATIC STAGE 4 COLORECTAL CARCINOMA' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 19:36:52
Data point term sent to Coder	System	24 Feb 2021 19:35:15
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 19:34:57
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 19:34:57
User entered 'metastaticstage 4 COLORECTAL CARCINOMA' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 19:34:57
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colorectal cancer, LLT: Colorectal carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 16:28:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 16:28:46
Data point term sent to Coder	System	04 Feb 2021 16:28:17
User entered 'Colorectal Carcinoma'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0516993

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0516994

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '19 Jan 2021'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0516997

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0516998

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered empty.	System	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0516999

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517001

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517002

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:38:33
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:06:06
User entered empty.	System	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:43:05
DataPoint Un-verified.	Matthew Musikanth (b) (4)	16 Feb 2021 23:35:45
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Feb 2021 23:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:43:09
DataPoint Un-verified.	Matthew Musikanth (b) (4)	16 Feb 2021 23:35:45
User entered '1' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Feb 2021 23:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517008

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517009

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517010

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517011

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517012

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '1'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517015

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517016

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517017

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 11:47:48
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'Patient had not received any treatment yet at the time of reporting and patient withdrawal. Patient to receive future treatment but has withdrawn from the study.' (Site from DM).	Matthew Musikanth (b) (4)	19 Feb 2021 16:40:44
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 03:38:47
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '1'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517019

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517020

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:31:12
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'subject has withdrawn consent outcome is unknown ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 23:15:24
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:07:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517022

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517023

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User closed query 'PV Query: It was confirmed the event of colorectal carcinoma was stage 4 that metastasized to bilateral lungs. Please consider updating the event term to be more specific to the diagnosis, if applicable' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 19:12:20
Query 'PV Query: It was confirmed the event of colorectal carcinoma was stage 4 that metastasized to bilateral lungs. Please consider updating the event term to be more specific to the diagnosis, if applicable' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	24 Feb 2021 20:04:19
User opened query 'PV Query: It was confirmed the event of colorectal carcinoma was stage 4 that metastasized to bilateral lungs. Please consider updating the event term to be more specific to the diagnosis, if applicable' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 19:20:00
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:44:28
DataPoint Un-verified.	Matthew Musikanth (b) (4)	16 Feb 2021 23:37:10
User entered 'REPORTED NEW MALIGNANCY, STAGE AND EXTENT NOT DETERMINED. Pt. reported update on colorectal carcinoma, diagnosis of stage 4, metastasized to bilateral lungs. Updated grade and SAE criteria.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Feb 2021 23:37:10
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 23:01:14
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)	16 Feb 2021 17:31:31

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:31:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:31:26
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:31:22
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:31:19
User closed query 'PV Query: Please request information on family history including any history of cancers: ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:31:16
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 'no treatment ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 23:14:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'no results available ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 23:14:02

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'none' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 23:13:35
Query 'PV Query: Please request information on family history including any history of cancers: ' answered with 'subject has family hx of cancer his (b) (6) had colon cancer in 2013' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 23:13:28
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'medical hx added ' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:11:28
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so' answered with 'MHx added' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	15 Feb 2021 22:10:32
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)	12 Feb 2021 23:08:24
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:07:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:07:01

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' canceled (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:03:57
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:03:43
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:03:14
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:02:46
User opened query 'PV Query: Please request information on family history including any history of cancers: ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 23:02:25
User entered 'Reported new malignancy, stage and extent not determined.'	Matthew Musikanth (b) (4)	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517027

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered '1'	System	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517028

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered '1'	System	04 Feb 2021 16:28:05

FDA-CBER-2022-1614-0517029

US3112221
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:10:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25

FDA-CBER-2022-1614-0517030

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 09 Jun 2021 15:10:42
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:08
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 17:02:58

US3112221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:02:42
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:08:19
Data point term sent to Coder	System	08 Apr 2021 20:46:11
User closed query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	08 Apr 2021 20:45:43
Query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'updated' (Site from System).	Brenda Grande (b) (4) (b) (4)	08 Apr 2021 20:45:43
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	08 Apr 2021 20:45:20
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	08 Apr 2021 20:45:20
User entered 'NYQUIL LIQUID (acetaminophen, dextromethorphan HBr, doxylamine succinate)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	08 Apr 2021 20:45:20
User opened query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:59:41

US3112221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:42

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 04:47:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 04:47:38
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 22:50:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 22:50:41
Data point term sent to Coder	System	15 Dec 2020 00:50:16
User entered 'Nyquil Liquid'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517034

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Viral Syndrome'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517035

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '30'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'mL (mL)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517038

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User closed query 'Per CDM: Please confirm if this is every 6 minutes, 6 hours, 6 days or etc.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 03:53:29
Query 'Per CDM: Please confirm if this is every 6 minutes, 6 hours, 6 days or etc.' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	12 Apr 2021 20:03:30
Signature has been broken.	Matthew Musikanth (b) (4)	12 Apr 2021 20:01:50
User entered 'Q6hrs' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	12 Apr 2021 20:01:50
User opened query 'Per CDM: Please confirm if this is every 6 minutes, 6 hours, 6 days or etc.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 19:40:14
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'q6'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517040

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517041

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '04 Dec 2020'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517043

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517044

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517045

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '07 Dec 2020'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517046

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:49:51

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered empty.	System	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517048

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered empty.	System	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517049

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:10:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered empty.	System	15 Dec 2020 00:49:51

FDA-CBER-2022-1614-0517050

US3112221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 00:53:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 00:53:46
Data point term sent to Coder	System	15 Dec 2020 00:53:17
User entered 'Ibuprofen'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517052

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Viral Syndrome'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517053

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '400'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517054

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517055

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517059

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '03 Dec 2020'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517061

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '0'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517062

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517063

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '08 Dec 2020'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517064

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	15 Dec 2020 00:53:14

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User entered '2'	System	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517066

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User entered '1'	System	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517067

US3112221
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:10:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:51
User entered '804 (804)'	System	15 Dec 2020 00:53:14

FDA-CBER-2022-1614-0517068

US3112221
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 15:10:42
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'No (N)'	Matthew Musikanth (b) (4)	16 Feb 2021 23:23:18

FDA-CBER-2022-1614-0517069

US3112221
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 15:10:42
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '09 Feb 2021'	Matthew Musikanth (b) (4)	09 Feb 2021 18:54:26

FDA-CBER-2022-1614-0517070

US3112221
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 15:10:42
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Matthew Musikanth (b) (4)	09 Feb 2021 18:54:26

FDA-CBER-2022-1614-0517071

US3112221

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:10:42

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered 'Patient decision to withdraw consent as continued participation/vaccination will be complicated with upcoming move to receive treatment of recent colorectal cancer diagnosis.'	Matthew Musikanth (b) (4)	09 Feb 2021 18:54:26

US3112221
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 15:10:42
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	09 Feb 2021 18:54:26

US3112221
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 15:10:42
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	09 Feb 2021 18:54:26

FDA-CBER-2022-1614-0517074

US3112221
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 15:10:42
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	09 Feb 2021 18:54:26

FDA-CBER-2022-1614-0517075

US3112221
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 15:10:42
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:55:18
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered empty.	Matthew Musikanth (b) (4)	09 Feb 2021 18:54:26

FDA-CBER-2022-1614-0517076

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'USA-US062-2021-MRNA-1273-P301000010'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517077

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517079

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:09:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:11:45
Un-reviewed for Safety.	System	16 Feb 2021 23:35:45
DataPoint Un-verified.	System	16 Feb 2021 23:35:45
User entered 'Yes (Y)'	System	16 Feb 2021 23:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517081

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517082

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517083

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517084

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Laurie'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517085

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Han-Conrad'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517086

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '9040 Friars Rd St 540'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517087

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'San Diego'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517088

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'CA'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517089

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '92108'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517090

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:32:01
User entered 'US'	System	05 Feb 2021 13:14:40

FDA-CBER-2022-1614-0517091

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered '4'	System	25 Feb 2021 19:12:42
User entered '3'	System	17 Feb 2021 15:11:40
User entered '2'	System	16 Feb 2021 17:32:13
User entered '1'	System	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'USA-US062-2021-MRNA-1273-P301000010'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517093

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517094

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517095

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:09:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:11:45
Un-reviewed for Safety.	System	16 Feb 2021 23:35:45
DataPoint Un-verified.	System	16 Feb 2021 23:35:45
User entered 'Yes (Y)'	System	16 Feb 2021 23:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517097

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517098

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517099

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517100

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Laurie'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517101

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Han-Conrad'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517102

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '9040 Friars Rd St 540'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517103

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'San Diego'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'CA'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517105

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '92108'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517106

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:32:01
User entered 'US'	System	05 Feb 2021 13:14:40

FDA-CBER-2022-1614-0517107

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered '4'	System	25 Feb 2021 19:12:42
User entered '3'	System	17 Feb 2021 15:11:40
User entered '2'	System	16 Feb 2021 17:32:13
User entered '1'	System	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 15:10:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
User entered '05/Feb/2021 08:14'	System	05 Feb 2021 13:14:40

FDA-CBER-2022-1614-0517109

US3112221

Folder: SAE USA-US062-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:32:01
User entered '1'	(b) (4), (b) (6)	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'USA-US062-2021-MRNA-1273-P301000010'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517111

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517113

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:09:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:11:45
Un-reviewed for Safety.	System	16 Feb 2021 23:35:45
DataPoint Un-verified.	System	16 Feb 2021 23:35:45
User entered 'Yes (Y)'	System	16 Feb 2021 23:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517115

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517116

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517117

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517118

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Laurie'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517119

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Han-Conrad'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517120

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '9040 Friars Rd St 540'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517121

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'San Diego'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517122

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'CA'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517123

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '92108'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517124

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:32:01
User entered 'US'	System	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered '4'	System	25 Feb 2021 19:12:42
User entered '3'	System	17 Feb 2021 15:11:40
User entered '2'	System	16 Feb 2021 17:32:13
User entered '1'	System	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 15:10:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
User entered '16/Feb/2021 11:32'	System	16 Feb 2021 17:32:13

US3112221

Folder: SAE USA-US062-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:11:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
User entered '1'	(b) (4), (b) (6)	16 Feb 2021 17:32:13

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'USA-US062-2021-MRNA-1273-P301000010'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517129

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517131

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:09:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:11:45
Un-reviewed for Safety.	System	16 Feb 2021 23:35:45
DataPoint Un-verified.	System	16 Feb 2021 23:35:45
User entered 'Yes (Y)'	System	16 Feb 2021 23:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517133

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517134

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517135

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517136

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Laurie'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517137

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Han-Conrad'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517138

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '9040 Friars Rd St 540'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517139

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'San Diego'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517140

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'CA'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517141

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '92108'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517142

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:32:01
User entered 'US'	System	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered '4'	System	25 Feb 2021 19:12:42
User entered '3'	System	17 Feb 2021 15:11:40
User entered '2'	System	16 Feb 2021 17:32:13
User entered '1'	System	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 15:10:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '17/Feb/2021 10:11'	System	17 Feb 2021 15:11:40

US3112221

Folder: SAE USA-US062-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:11:45
User entered '1'	(b) (4), (b) (6)	17 Feb 2021 15:11:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'USA-US062-2021-MRNA-1273-P301000010'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517147

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517148

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517149

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 23:09:49
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:11:45
Un-reviewed for Safety.	System	16 Feb 2021 23:35:45
DataPoint Un-verified.	System	16 Feb 2021 23:35:45
User entered 'Yes (Y)'	System	16 Feb 2021 23:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517151

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517152

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'No (N)'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517153

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Yes (Y)'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Laurie'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517155

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'Han-Conrad'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517156

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '9040 Friars Rd St 540'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517157

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'San Diego'	System	05 Feb 2021 13:14:19

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered 'CA'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517159

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 13:14:35
User entered '92108'	System	05 Feb 2021 13:14:19

FDA-CBER-2022-1614-0517160

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:17:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:57:15
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 17:32:01
User entered 'US'	System	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 09 Jun 2021 15:10:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User entered '4'	System	25 Feb 2021 19:12:42
User entered '3'	System	17 Feb 2021 15:11:40
User entered '2'	System	16 Feb 2021 17:32:13
User entered '1'	System	05 Feb 2021 13:14:40

US3112221
Folder: SAE USA-US062-2021-MRNA-1273-P301000010
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 15:10:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '25/Feb/2021 14:12'	System	25 Feb 2021 19:12:42

FDA-CBER-2022-1614-0517163

US3112221

Folder: SAE USA-US062-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:10:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:25:25
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	05 Mar 2021 19:17:49
User entered '1'	(b) (4), (b) (6)	25 Feb 2021 19:12:42