US3322199 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

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US3322199
Form: Participant Creation
Data signed: (b) (4) **26 Feb 2021 03:29:20**
Generated On: 09 Jun 2021 17:07:17

Participant ID	US3322199

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0775751

US3322199
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0775752

US3322199
Folder: Screening
Form: Demographics
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
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-2022-1614-0775753

US3322199
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Date of Informed Consent *(dd MMM yyyy)*	2 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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-2022-1614-0775754

US3322199
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775755

US3322199
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **26 Feb 2021 03:29:21**
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Were any significant conditions reported?	Yes ■ No ☐

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US3322199
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN SEP 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0775757

US3322199
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	BONE SPUR SURGERY
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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US3322199
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	ARRHYTHMIA (SUPRAVENTRICULAR TACHYCARDIA)
Start date (dd MMM yyyy)	UN JAN 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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US3322199
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1959
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 1959
Start Year (derived)	1959
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0775760

US3322199
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	BACK SURGERY
Start date (dd MMM yyyy)	31 OCT 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	31 OCT 2017
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	OCT 2017
Stop Year (derived)	2017

FDA-CBER-2022-1614-0775761

US3322199
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	ECZEMA
Start date (dd MMM yyyy)	UN SEP 2016
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)	SEP 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0775762

US3322199
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	LEFT BUNDLE BRANCH BLOCK
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	

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US3322199
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	PRE-DIABETES
Start date (dd MMM yyyy)	UN FEB 2019
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)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0775764

US3322199
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	BONE SPUR
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

FDA-CBER-2022-1614-0775765

US3322199
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Condition	HYPERCHOLESTEREMIA
Start date (dd MMM yyyy)	UN JAN 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0775766

US3322199
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
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Condition	OBESITY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0775767

US3322199
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	2 SEP 2020
Time of assessment *(00:00-23:59)*	15:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:00
Height *(xxx.x)*	71 in
Weight *(xxx.x)*	225 lb
BMI *(xxx.x)*	31.44675 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-2022-1614-0775768

US3322199
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **26 Feb 2021 03:29:21**
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Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	2 SEP 2020

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

FDA-CBER-2022-1614-0775769

US3322199
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **26 Feb 2021 03:29:21**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ■
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ■ No ☐
Other	Yes ■ No ☐
Specify	NETWORK ADMINISTRATOR (IT FIELD) IN A SCHOOL.

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

US3322199
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **26 Feb 2021 03:29:21**
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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	- INTERACTS WITH 5+ PEOPLE ON A WORK DAY - GOES TO WORK 5/WEEK - PLACE OF WORSHIP 1+/WEEK - STORES 2+/WEEK - ATTENDS GATHERINGS OF 10 + PEOPLE 2 OR MORE TIMES A MONTH

FDA-CBER-2022-1614-0775771

US3322199
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0775772

US3322199
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **26 Feb 2021 03:29:21**
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What was the date of randomization? *(dd MMM yyyy)*	02 SEP 2020
What was the participant's randomization number?	111240
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-2022-1614-0775773

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
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Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0775774

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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)*	2 SEP 2020
Time of assessment *(00:00-23:59)*	15:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:00
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0775775

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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)*	2 SEP 2020
Time of assessment *(00:00-23:59)*	17:17 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 17:17
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0775776

US3322199
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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-2022-1614-0775777

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	2 SEP 2020
What was the treatment time? *(00:00-23:59)*	16:42 (24 HR)
Treatment Date and Time (derived)	2 SEP 2020 16:42
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-2022-1614-0775778

US3322199
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	2 SEP 2020
Collection time *(00:00-23:59)*	16:18 (24 HR)
Collection date and time (derived)	2 SEP 2020 16:18

FDA-CBER-2022-1614-0775779

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Collection date *(dd MMM yyyy)*			2 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:15	2 SEP 2020 16:15
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0775780

US3322199
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-0775781

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**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 SEP 2020 17:21
PC Open Date & Time	02 SEP 2020 17:02
PC Close Date & Time	02 SEP 2020 19:32

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	02 SEP 2020 22:13
PC Open Date & Time	02 SEP 2020 20:27
PC Close Date & Time	03 SEP 2020 11:59

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17

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**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 SEP 2020 23:31
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17

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

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °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	05 SEP 2020 22:08
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0775786

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 SEP 2020 18:38
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17

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	07 SEP 2020 19:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

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	08 SEP 2020 18:31
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	02 SEP 2020 17:22
PC Open Date & Time	02 SEP 2020 17:02
PC Close Date & Time	02 SEP 2020 19:32

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US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	02 SEP 2020 22:13
PC Open Date & Time	02 SEP 2020 20:27
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-0775791

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17

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	03 SEP 2020 23:31
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0775792

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	04 SEP 2020 18:18
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-0775793

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17

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	05 SEP 2020 22:08
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0775794

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	06 SEP 2020 18:38
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-0775795

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	07 SEP 2020 19:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0775796

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17

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	08 SEP 2020 18:31
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-0775797

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 ☐

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	02 SEP 2020 17:22
PC Open Date & Time	02 SEP 2020 17:02
PC Close Date & Time	02 SEP 2020 19:32

FDA-CBER-2022-1614-0775799

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 ☐

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	02 SEP 2020 22:14
PC Open Date & Time	02 SEP 2020 20:27
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-0775801

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 ■

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	03 SEP 2020 23:32
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-0775803

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 ■

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	04 SEP 2020 18:19
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-0775805

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 ■

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	05 SEP 2020 22:08
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-0775807

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 ■

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	06 SEP 2020 18:39
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-0775809

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775810

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	07 SEP 2020 19:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-0775811

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775812

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	08 SEP 2020 18:31
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-0775813

US3322199
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775814

US3322199
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775815

US3322199
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775816

US3322199
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775817

US3322199
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775818

US3322199
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775819

US3322199
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0775820

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	1 OCT 2020
Time of assessment *(00:00-23:59)*	11:15 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 11:15
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0775821

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	1 OCT 2020
Time of assessment *(00:00-23:59)*	12:24 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 12:24
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0775822

US3322199
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	1 OCT 2020

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

FDA-CBER-2022-1614-0775823

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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)*	1 OCT 2020
What was the treatment time? *(00:00-23:59)*	11:52 (24 HR)
Treatment Date and Time (derived)	1 OCT 2020 11:52
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-2022-1614-0775824

US3322199
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	1 OCT 2020
Collection time *(00:00-23:59)*	11:40 (24 HR)
Collection date and time (derived)	1 OCT 2020 11:40

FDA-CBER-2022-1614-0775825

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Collection date *(dd MMM yyyy)*			1 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:35	1 OCT 2020 11:35
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0775826

US3322199
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775827

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	01 OCT 2020 12:28
PC Open Date & Time	01 OCT 2020 12:12
PC Close Date & Time	01 OCT 2020 14:42

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■

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

PC Time Stamp	01 OCT 2020 19:02
PC Open Date & Time	01 OCT 2020 15:37
PC Close Date & Time	02 OCT 2020 11:59

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17

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	02 OCT 2020 19:01
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 OCT 2020 19:43
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	04 OCT 2020 20:32
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17

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**	97.8 °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	05 OCT 2020 19:01
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 OCT 2020 19:01
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17

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	07 OCT 2020 19:48
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17

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	01 OCT 2020 12:28
PC Open Date & Time	01 OCT 2020 12:12
PC Close Date & Time	01 OCT 2020 14:42

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US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17

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	01 OCT 2020 19:03
PC Open Date & Time	01 OCT 2020 15:37
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0775837

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17

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	02 OCT 2020 19:01
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0775838

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17

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	03 OCT 2020 19:43
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0775839

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17

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	04 OCT 2020 20:32
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-0775840

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17

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	05 OCT 2020 19:01
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-0775841

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17

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	06 OCT 2020 19:02
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-0775842

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17

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	07 OCT 2020 19:49
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-0775843

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 ☐

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 OCT 2020 12:29
PC Open Date & Time	01 OCT 2020 12:12
PC Close Date & Time	01 OCT 2020 14:42

FDA-CBER-2022-1614-0775845

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 ☐

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 OCT 2020 19:04
PC Open Date & Time	01 OCT 2020 15:37
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0775847

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 ■

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	02 OCT 2020 19:01
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0775849

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17

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 ■

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17

	Yes ☐
PC Time stamp	03 OCT 2020 19:44
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0775851

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775852

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17

	Yes ☐
PC Time stamp	04 OCT 2020 20:33
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-0775853

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 ■

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	05 OCT 2020 19:01
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-0775855

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 ■

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17

	Yes
PC Time stamp	06 OCT 2020 19:02
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-0775857

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 ■

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17

	Yes ☐
PC Time stamp	07 OCT 2020 19:49
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-0775859

US3322199
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	MULTIPLE UNSUCCESSFUL ATTEMPTS, PATIENT FINALLY RESPONDED ON 13-OCT-2020, OUT OF WINDOW

FDA-CBER-2022-1614-0775860

US3322199
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775861

US3322199
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775862

US3322199
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775863

US3322199
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775864

US3322199
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775865

US3322199
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775866

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	30 OCT 2020
Time of assessment *(00:00-23:59)*	11:19 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 11:19
Temperature *(xxx.x)*	96.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	47 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-0775867

US3322199
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	30 OCT 2020

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

FDA-CBER-2022-1614-0775868

US3322199
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	30 OCT 2020
Collection time *(00:00-23:59)*	11:45 (24 HR)
Collection date and time (derived)	30 OCT 2020 11:45

FDA-CBER-2022-1614-0775869

US3322199
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775870

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 15:48:50
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

FDA-CBER-2022-1614-0775871

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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17

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

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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17

Please contact your study clinic immediately. Click below to confirm that you have read this 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

FDA-CBER-2022-1614-0775875

US3322199
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 17:07:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

FDA-CBER-2022-1614-0775876

US3322199
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17

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-2022-1614-0775877

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

US3322199
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:07:17

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
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-2022-1614-0775879

US3322199
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 17:07:17

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-0775880

US3322199
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775881

US3322199
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 17:07:17

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	
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)*	
Participant randomization assignment	mRNA-1273 ☐ Placebo ☐
Actual Dose 1	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☐
Placebo Only Flag	
Continuing with mRNA-1273	

FDA-CBER-2022-1614-0775882

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

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

US3322199
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **26 Feb 2021 03:29:20**
Generated On: 09 Jun 2021 17:07:17

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0775885

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **26 Feb 2021 03:29:20**
Generated On: 09 Jun 2021 17:07:17

AEID	USA-US060-2020-MRNA-1273-P30 1000012
Adverse event	FATAL MYOCARDIAL INFARCTION
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)*	16 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)*	16 NOV 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	True
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	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	

SAE TERM: MYOCARDIAL INFARCTION
OUTCOME: FATAL
CAUSALITY: NOT IP RELATED
VACCINATION #1: 02-SEP-2020
VACCINATION #2: 01-OCT-2020
C3: 30-OCT-2020

SUBJECT'S SISTER CALLED OUR SITE TO INFORM THAT SUBJECT PASSED AWAY ON 16-NOV-2020 FROM A MASSIVE HEART ATTACK. SUBJECT HAD MULTIPLE CARDIAC RISK FACTORS INCLUDING HYPERTENSION (2018), PRE-DIABETES (2019), SUPRAVENTRICULAR TACHYCARDIA (2019), OBESITY, HYPERLIPIDEMIA (2019), LEFT BUNDLE BRANCH BLOCK (1976). FURTHER DETAILS NOT AVAILABLE. MEDICAL RECORDS BEING REQUESTED
THERE IS INSUFFICIENT INFORMATION TO DETERMINE IF THERE WERE ANY NEW CONCOMITANT MEDICATIONS, NON-STUDY VACCINATIONS, PROHIBITED MEDICATIONS, OR COVID SYMPTOMS. DOES NOT APPEAR TO BE COVID-19 RELATED SINCE SUBJECT'S SISTER REPORTED A MAJOR HEART ATTACK. MEDICAL RECORDS PENDING.

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)	

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

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

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

FDA-CBER-2022-1614-0775889

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **26 Feb 2021 03:29:20**
Generated On: 09 Jun 2021 17:07:17

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JAN 2019
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **26 Feb 2021 03:29:20**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775892

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN OCT 2019
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **26 Feb 2021 03:29:20**
Generated On: 09 Jun 2021 17:07:17

Name of Medication	ASPIRIN
Prophylaxis	Yes ■ No ☐
Indication	CARDIAC PROPHYLAXIS
Dose per administration	81
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0775894

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JAN 2019
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **26 Feb 2021 03:29:20**
Generated On: 09 Jun 2021 17:07:17

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

FDA-CBER-2022-1614-0775896

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JAN 2019
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3322199
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0775898

US3322199
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

Date of study discontinuation/completion *(dd MMM yyyy)*	16 NOV 2020
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ■ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	
If reason for discontinuation is Death, main cause of death	Adverse event ■ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	16 NOV 2020
Was autopsy performed?	Yes ☐ No ☐ Unknown ■

FDA-CBER-2022-1614-0775899

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

SAEID	USA-US060-2020-MRNA-1273-P301000012
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form (1)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

SAEID	USA-US060-2020-MRNA-1273-P301000012
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	23/NOV/2020 18:35
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

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form (2)
Data signed: (b) (4) **26 Feb 2021 03:29:21**
Generated On: 09 Jun 2021 17:07:17

SAEID	USA-US060-2020-MRNA-1273-P301000012
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	08/DEC/2020 12:23
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

US3322199 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322199
Form: Participant Creation
Generated On: 09 Jun 2021 17:07:17
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'US3322199'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:54:15

FDA-CBER-2022-1614-0775904

US3322199
Form: Participant Creation
Generated On: 09 Jun 2021 17:07:17

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01

FDA-CBER-2022-1614-0775905

US3322199
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:35

FDA-CBER-2022-1614-0775906

US3322199
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:54:16

FDA-CBER-2022-1614-0775907

US3322199
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:35

FDA-CBER-2022-1614-0775908

US3322199
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'SCRN'	System	03 Sep 2020 14:42:35

FDA-CBER-2022-1614-0775909

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:54:17

FDA-CBER-2022-1614-0775910

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '64'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775911

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User entered 'YEARS'	System	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775912

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User entered '64'	System	02 Sep 2020 21:39:43

FDA-CBER-2022-1614-0775913

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Male (M)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775914

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775915

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775916

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775917

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775918

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775919

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775920

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775921

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775922

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775923

US3322199
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:07:17
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:42:58

FDA-CBER-2022-1614-0775924

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

FDA-CBER-2022-1614-0775925

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User entered 'Sep 2020'	System	02 Sep 2020 21:39:43

FDA-CBER-2022-1614-0775926

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User entered '2020'	System	02 Sep 2020 21:39:43

FDA-CBER-2022-1614-0775927

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Amendment 3 (3)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

FDA-CBER-2022-1614-0775928

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

FDA-CBER-2022-1614-0775929

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

FDA-CBER-2022-1614-0775930

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

FDA-CBER-2022-1614-0775931

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:43

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:54:16

FDA-CBER-2022-1614-0775933

US3322199
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:07:17
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User entered '1'	System	02 Sep 2020 21:39:50

FDA-CBER-2022-1614-0775934

US3322199
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 17:07:17
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:39:50

FDA-CBER-2022-1614-0775935

US3322199
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 17:07:17
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:33

FDA-CBER-2022-1614-0775936

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:44:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:44:46
Data point term sent to Coder	System	03 Sep 2020 14:44:07
User entered 'Hypertension'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775937

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN Sep 2018'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775938

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775939

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775940

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775941

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775942

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Sep 2018'	System	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775943

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2018'	System	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775944

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775945

US3322199
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:43:56

FDA-CBER-2022-1614-0775946

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:37:11
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'ASSOCIATED CONDITION, BONE SPUR, ADDED TO MED HISTORY ECRF' (Site from DM).	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:40:51
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 14:56:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone lesion excision, LLT: Bone spur removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:45:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:45:49
Data point term sent to Coder	System	03 Sep 2020 14:45:07
User entered 'Bone Spur Surgery'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775947

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN UNK 2012'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775948

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775949

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775950

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN UNK 2012'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775951

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775952

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Jan 2012'	System	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775953

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2012'	System	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775954

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Jan 2012'	System	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775955

US3322199
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2012'	System	03 Sep 2020 14:44:37

FDA-CBER-2022-1614-0775956

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Supraventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:08:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:08:45
Data point term sent to Coder	System	03 Sep 2020 14:48:16
User entered 'Arrhythmia (Supraventricular tachycardia)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775957

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN Jan 2019'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775958

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775959

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775960

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775961

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775962

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Jan 2019'	System	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775963

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2019'	System	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775964

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775965

US3322199
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:47:58

FDA-CBER-2022-1614-0775966

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:48:51
Data point term sent to Coder	System	03 Sep 2020 14:48:17
User entered 'Penicillin Allergy'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775967

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN UNK 1959'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775968

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775969

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775970

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775971

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775972

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Jan 1959'	System	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775973

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '1959'	System	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775974

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775975

US3322199
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:48:13

FDA-CBER-2022-1614-0775976

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:49:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:49:42
Data point term sent to Coder	System	03 Sep 2020 14:49:18
User entered 'Back Surgery'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775977

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '31 Oct 2017'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775978

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775979

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775980

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '31 Oct 2017'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775981

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775982

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Oct 2017'	System	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775983

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2017'	System	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775984

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Oct 2017'	System	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775985

US3322199
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2017'	System	03 Sep 2020 14:48:42

FDA-CBER-2022-1614-0775986

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
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)	03 Sep 2020 14:49:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:49:43
Data point term sent to Coder	System	03 Sep 2020 14:49:19
User entered 'Eczema'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775987

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN Sep 2016'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775988

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775989

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775990

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775991

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775992

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Sep 2016'	System	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775993

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2016'	System	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775994

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775995

US3322199
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:49:06

FDA-CBER-2022-1614-0775996

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Bundle branch block left, LLT: Left bundle branch block - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:50:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:50:49
Data point term sent to Coder	System	03 Sep 2020 14:50:20
User entered 'Left Bundle Branch Block'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0775997

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN UNK 1976'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0775998

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0775999

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0776000

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0776001

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0776002

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Jan 1976'	System	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0776003

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '1976'	System	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0776004

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0776005

US3322199
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 14:49:44

FDA-CBER-2022-1614-0776006

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:03:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:03:52
Data point term sent to Coder	System	15 Oct 2020 15:00:11
User entered 'Pre-Diabetes'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776007

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN Feb 2019'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776008

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776009

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776010

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776011

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776012

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Feb 2019'	System	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776013

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2019'	System	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776014

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776015

US3322199
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	15 Oct 2020 14:59:25

FDA-CBER-2022-1614-0776016

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Exostosis, LLT: Bone spur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 20:49:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 20:49:32
Data point term sent to Coder	System	15 Oct 2020 20:40:54
User entered 'BONE SPUR'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776017

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776018

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776019

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776020

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'UN UNK 2012'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Blessing Felix-Okoroji (b) (4)	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776022

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776023

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776024

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Jan 2012'	System	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776025

US3322199
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2012'	System	15 Oct 2020 20:39:59

FDA-CBER-2022-1614-0776026

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesteremia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:17:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:17:28
Data point term sent to Coder	System	19 Oct 2020 21:16:21
User entered 'hypercholesteremia'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776027

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'un Jan 2019'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776028

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776029

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776030

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776031

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776032

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'Jan 2019'	System	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776033

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2019'	System	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776034

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776035

US3322199
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	19 Oct 2020 21:16:05

FDA-CBER-2022-1614-0776036

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 22:42:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 22:42:20
Data point term sent to Coder	System	07 Dec 2020 22:41:31
User entered 'Obesity'	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776037

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776038

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1'	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776039

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776040

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776041

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776042

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776043

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776044

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776045

US3322199
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:07:17
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	07 Dec 2020 22:40:48

FDA-CBER-2022-1614-0776046

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776047

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776048

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '15:00'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776049

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2 Sep 2020 15:00'	System	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776050

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '71' in	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24
DataPoint set to visible.	System	02 Sep 2020 21:39:50

FDA-CBER-2022-1614-0776051

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '225' lb	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24
DataPoint set to visible.	System	02 Sep 2020 21:39:50

FDA-CBER-2022-1614-0776052

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '31.44675'	System	03 Sep 2020 14:52:24
DataPoint set to visible.	System	02 Sep 2020 21:39:50

FDA-CBER-2022-1614-0776053

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'kg/m2'	System	03 Sep 2020 14:52:24
DataPoint set to visible.	System	02 Sep 2020 21:39:50

FDA-CBER-2022-1614-0776054

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776055

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776056

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776057

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776058

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'bpm'	System	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776059

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776060

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'breaths/min'	System	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776061

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776062

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'mmHg'	System	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776063

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776064

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'mmHg'	System	03 Sep 2020 14:52:24

FDA-CBER-2022-1614-0776065

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30

FDA-CBER-2022-1614-0776066

US3322199
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30

FDA-CBER-2022-1614-0776067

US3322199
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:07:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:32

FDA-CBER-2022-1614-0776068

US3322199
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:07:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:52:32

FDA-CBER-2022-1614-0776069

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776070

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776071

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17

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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776072

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776073

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776074

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17

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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776075

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776077

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776078

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776079

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776081

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Network Administrator (IT Field) in a school.'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776082

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776083

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776084

US3322199

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:17

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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776086

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17

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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776087

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776088

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776089

US3322199
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:07:17
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '- interacts with 5+ people on a work day - goes to work 5/week - place of worship 1+/week - stores 2+/week - attends gatherings of 10 + people 2 or more times a month'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:53:38

FDA-CBER-2022-1614-0776090

US3322199
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 15:01:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:01:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:01:40
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 14:59:56
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:59:56

FDA-CBER-2022-1614-0776091

US3322199
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:01:40
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:59:56

FDA-CBER-2022-1614-0776092

US3322199
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:01:40
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 14:59:56

FDA-CBER-2022-1614-0776093

US3322199
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'VISIT1'	System	03 Sep 2020 15:01:40
User entered empty.	System	03 Sep 2020 14:59:56

FDA-CBER-2022-1614-0776094

US3322199
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:07:17
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:59:31

FDA-CBER-2022-1614-0776095

US3322199
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:07:17
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '111240'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:59:31

FDA-CBER-2022-1614-0776096

US3322199
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:07:17
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 20:59:31

FDA-CBER-2022-1614-0776097

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:17

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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

US3322199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:17

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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

US3322199
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:07:17
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

FDA-CBER-2022-1614-0776100

US3322199
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:07:17
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

FDA-CBER-2022-1614-0776101

US3322199
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:07:17
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:03:07

FDA-CBER-2022-1614-0776102

US3322199
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:07:17
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:14:36
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:02:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:02:03

FDA-CBER-2022-1614-0776103

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:07:17
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:07:17
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776105

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:07:17
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776106

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:07:17
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776107

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User accepted default value 'Pre-Dose (PREDOSE)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776108

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776109

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776110

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '15:00'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776111

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2 Sep 2020 15:00'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776112

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776113

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776114

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776115

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '60'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776116

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'bpm'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776117

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '15'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776118

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'breaths/min'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776119

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '123'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776120

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'mmHg'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776121

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '75'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776122

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'mmHg'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776123

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:07:17
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776124

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:07:17
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User accepted default value 'Post-Dose (POSTDOSE)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776126

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776127

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776128

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 18:51:18
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' answered with 'PER PROTOCOL 8.2.5 VITAL SIGN MEASUREMENTS "On Day 1 and Day 29, vital sign measurements will be collected once before IP injection and at least 30 minutes after IP injection (before participants are discharged from the study site)." THANK YOU.' (Site from DM).		10 Sep 2020 21:26:48
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).		09 Sep 2020 21:34:56
User entered '17:17'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776129

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2 Sep 2020 17:17'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776130

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '97.2' F	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776131

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776132

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776133

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '58'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776134

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'bpm'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776135

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '15'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776136

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'breaths/min'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776137

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '135'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776138

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'mmHg'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776139

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '71'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776140

US3322199
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'mmHg'	System	03 Sep 2020 15:06:34

FDA-CBER-2022-1614-0776141

US3322199
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:07:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:46

FDA-CBER-2022-1614-0776142

US3322199
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:07:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:06:46

FDA-CBER-2022-1614-0776143

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776144

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776145

US3322199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:17

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 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776147

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776148

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '16:42'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776149

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2 Sep 2020 16:42'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776150

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4) (b) (4)	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776151

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'ONCE'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776152

US3322199
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776153

US3322199
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:10

FDA-CBER-2022-1614-0776154

US3322199
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:10

FDA-CBER-2022-1614-0776155

US3322199
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '16:18'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:10

FDA-CBER-2022-1614-0776156

US3322199
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2 Sep 2020 16:18'	System	03 Sep 2020 15:07:10

FDA-CBER-2022-1614-0776157

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:07:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2 Sep 2020'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776158

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:07:17
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776159

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:07:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776160

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:07:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '16:15'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776161

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:07:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '2 Sep 2020 16:15'	System	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776162

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:07:17
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776163

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:07:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776164

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:07:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776165

US3322199
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:07:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered empty.	System	03 Sep 2020 15:07:31

FDA-CBER-2022-1614-0776166

US3322199
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	03 Sep 2020 15:07:36

FDA-CBER-2022-1614-0776167

US3322199
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:30
User entered '1'	System	03 Sep 2020 15:07:36

FDA-CBER-2022-1614-0776168

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776169

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:20:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0370027b-d560-4bd9-9206-f12ce85b6169'	System	02 Sep 2020 22:21:32
User entered 'Yes (Y)'	System	02 Sep 2020 22:21:32

FDA-CBER-2022-1614-0776170

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:21:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0370027b-d560-4bd9-9206-f12ce85b6169'	System	02 Sep 2020 22:21:32
User entered '97.2'	System	02 Sep 2020 22:21:32

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:21:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0370027b-d560-4bd9-9206-f12ce85b6169'	System	02 Sep 2020 22:21:32
User entered 'No (N)'	System	02 Sep 2020 22:21:32

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:21:27', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0370027b-d560-4bd9-9206-f12ce85b6169'	System	02 Sep 2020 22:21:32
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 22:21:32

FDA-CBER-2022-1614-0776173

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 17:02'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776174

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 19:32'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776175

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776176

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f4592cfd-1b14-491f-a702-c319c25bd9fc'	System	03 Sep 2020 03:13:40
User entered 'Yes (Y)'	System	03 Sep 2020 03:13:40

FDA-CBER-2022-1614-0776177

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f4592cfd-1b14-491f-a702-c319c25bd9fc'	System	03 Sep 2020 03:13:40
User entered '97.8'	System	03 Sep 2020 03:13:40

FDA-CBER-2022-1614-0776178

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f4592cfd-1b14-491f-a702-c319c25bd9fc'	System	03 Sep 2020 03:13:40
User entered 'No (N)'	System	03 Sep 2020 03:13:40

FDA-CBER-2022-1614-0776179

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f4592cfd-1b14-491f-a702-c319c25bd9fc'	System	03 Sep 2020 03:13:40
User entered '02 Sep 2020 22:13'	System	03 Sep 2020 03:13:40

FDA-CBER-2022-1614-0776180

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 20:27'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776181

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776182

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 2'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776183

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b3094289-2d2e-461b-8eda-c38186dd4e20'	System	04 Sep 2020 04:31:29
User entered 'Yes (Y)'	System	04 Sep 2020 04:31:29

FDA-CBER-2022-1614-0776184

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:17', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b3094289-2d2e-461b-8eda-c38186dd4e20'	System	04 Sep 2020 04:31:29
User entered '97.4'	System	04 Sep 2020 04:31:29

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b3094289-2d2e-461b-8eda-c38186dd4e20'	System	04 Sep 2020 04:31:29
User entered 'No (N)'	System	04 Sep 2020 04:31:29

FDA-CBER-2022-1614-0776186

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b3094289-2d2e-461b-8eda-c38186dd4e20'	System	04 Sep 2020 04:31:29
User entered '03 Sep 2020 23:31'	System	04 Sep 2020 04:31:29

FDA-CBER-2022-1614-0776187

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776188

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776189

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 3'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776190

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:17:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5a3a66c1-3e2e-4be2-8f98-fad7ec937414'	System	04 Sep 2020 23:18:26
User entered 'Yes (Y)'	System	04 Sep 2020 23:18:26

FDA-CBER-2022-1614-0776191

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:07', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5a3a66c1-3e2e-4be2-8f98-fad7ec937414'	System	04 Sep 2020 23:18:26
User entered '97.6'	System	04 Sep 2020 23:18:26

FDA-CBER-2022-1614-0776192

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:12', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5a3a66c1-3e2e-4be2-8f98-fad7ec937414'	System	04 Sep 2020 23:18:26
User entered 'No (N)'	System	04 Sep 2020 23:18:26

FDA-CBER-2022-1614-0776193

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5a3a66c1-3e2e-4be2-8f98-fad7ec937414'	System	04 Sep 2020 23:18:26
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 23:18:26

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776195

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776196

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 4'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776197

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:07:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6df4399-116c-48be-b11e-bf83b2a843a5'	System	06 Sep 2020 03:08:05
User entered 'Yes (Y)'	System	06 Sep 2020 03:08:05

FDA-CBER-2022-1614-0776198

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:07:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6df4399-116c-48be-b11e-bf83b2a843a5'	System	06 Sep 2020 03:08:05
User entered '98.1'	System	06 Sep 2020 03:08:05

FDA-CBER-2022-1614-0776199

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:07:57', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6df4399-116c-48be-b11e-bf83b2a843a5'	System	06 Sep 2020 03:08:05
User entered 'No (N)'	System	06 Sep 2020 03:08:05

FDA-CBER-2022-1614-0776200

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:04', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6df4399-116c-48be-b11e-bf83b2a843a5'	System	06 Sep 2020 03:08:05
User entered '05 Sep 2020 22:08'	System	06 Sep 2020 03:08:05

FDA-CBER-2022-1614-0776201

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776202

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776203

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 5'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776204

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7652f5aa-eba2-4a45-95f6-2b776312e7c8'	System	06 Sep 2020 23:38:46
User entered 'Yes (Y)'	System	06 Sep 2020 23:38:46

FDA-CBER-2022-1614-0776205

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7652f5aa-eba2-4a45-95f6-2b776312e7c8'	System	06 Sep 2020 23:38:46
User entered '98.3'	System	06 Sep 2020 23:38:46

FDA-CBER-2022-1614-0776206

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:30', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7652f5aa-eba2-4a45-95f6-2b776312e7c8'	System	06 Sep 2020 23:38:46
User entered 'No (N)'	System	06 Sep 2020 23:38:46

FDA-CBER-2022-1614-0776207

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7652f5aa-eba2-4a45-95f6-2b776312e7c8'	System	06 Sep 2020 23:38:46
User entered '06 Sep 2020 18:38'	System	06 Sep 2020 23:38:46

FDA-CBER-2022-1614-0776208

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776209

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776210

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 6'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776211

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ad0da314-0823-4bbd-a2f9-9baf109fadb1'	System	08 Sep 2020 00:02:21
User entered 'Yes (Y)'	System	08 Sep 2020 00:02:21

FDA-CBER-2022-1614-0776212

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ad0da314-0823-4bbd-a2f9-9baf109fadb1'	System	08 Sep 2020 00:02:21
User entered '98.2'	System	08 Sep 2020 00:02:21

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:16', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ad0da314-0823-4bbd-a2f9-9baf109fadb1'	System	08 Sep 2020 00:02:21
User entered 'No (N)'	System	08 Sep 2020 00:02:21

FDA-CBER-2022-1614-0776214

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:20', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ad0da314-0823-4bbd-a2f9-9baf109fadb1'	System	08 Sep 2020 00:02:21
User entered '07 Sep 2020 19:02'	System	08 Sep 2020 00:02:21

FDA-CBER-2022-1614-0776215

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776216

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776217

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 7'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776218

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:30:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3a645577-5bc3-42b2-aaa6-77ff2ae7fa81'	System	08 Sep 2020 23:31:18
User entered 'Yes (Y)'	System	08 Sep 2020 23:31:18

FDA-CBER-2022-1614-0776219

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:05', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3a645577-5bc3-42b2-aaa6-77ff2ae7fa81'	System	08 Sep 2020 23:31:18
User entered '97.8'	System	08 Sep 2020 23:31:18

FDA-CBER-2022-1614-0776220

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3a645577-5bc3-42b2-aaa6-77ff2ae7fa81'	System	08 Sep 2020 23:31:18
User entered 'No (N)'	System	08 Sep 2020 23:31:18

FDA-CBER-2022-1614-0776221

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3a645577-5bc3-42b2-aaa6-77ff2ae7fa81'	System	08 Sep 2020 23:31:18
User entered '08 Sep 2020 18:31'	System	08 Sep 2020 23:31:18

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776223

US3322199
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776224

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776225

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:21:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered 'None (1)'	System	02 Sep 2020 22:22:18

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered 'No (N)'	System	02 Sep 2020 22:22:18

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:04', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered 'No (N)'	System	02 Sep 2020 22:22:18

FDA-CBER-2022-1614-0776228

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered 'None (1)'	System	02 Sep 2020 22:22:18

FDA-CBER-2022-1614-0776229

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:14', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '1dc499f4-6864-4ebd-a5dd-fc8edfe0020e'	System	02 Sep 2020 22:22:18
User entered '02 Sep 2020 17:22'	System	02 Sep 2020 22:22:18

FDA-CBER-2022-1614-0776230

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 17:02'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776231

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 19:32'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776232

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776233

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered 'None (1)'	System	03 Sep 2020 03:14:00

FDA-CBER-2022-1614-0776234

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:49', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered 'No (N)'	System	03 Sep 2020 03:14:00

FDA-CBER-2022-1614-0776235

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered 'No (N)'	System	03 Sep 2020 03:14:00

FDA-CBER-2022-1614-0776236

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered 'None (1)'	System	03 Sep 2020 03:14:00

FDA-CBER-2022-1614-0776237

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:13:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f2a659e3-123a-4d38-bf8f-0c0d5b4263a1'	System	03 Sep 2020 03:14:00
User entered '02 Sep 2020 22:13'	System	03 Sep 2020 03:14:00

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 20:27'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776239

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776240

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 2'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776241

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered 'None (1)'	System	04 Sep 2020 04:31:53

FDA-CBER-2022-1614-0776242

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered 'No (N)'	System	04 Sep 2020 04:31:53

FDA-CBER-2022-1614-0776243

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:44', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered 'No (N)'	System	04 Sep 2020 04:31:53

FDA-CBER-2022-1614-0776244

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:48', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered 'None (1)'	System	04 Sep 2020 04:31:53

FDA-CBER-2022-1614-0776245

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '33119366-2ef1-4f50-b0d8-eb6d697b261d'	System	04 Sep 2020 04:31:53
User entered '03 Sep 2020 23:31'	System	04 Sep 2020 04:31:53

FDA-CBER-2022-1614-0776246

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776247

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776248

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 3'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776249

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:48', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered 'None (1)'	System	04 Sep 2020 23:19:00

FDA-CBER-2022-1614-0776250

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:30', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered 'No (N)'	System	04 Sep 2020 23:19:00

FDA-CBER-2022-1614-0776251

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered 'No (N)'	System	04 Sep 2020 23:19:00

FDA-CBER-2022-1614-0776252

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered 'None (1)'	System	04 Sep 2020 23:19:00

FDA-CBER-2022-1614-0776253

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:18:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'feef276b-b345-4198-8c44-6226fab149e2'	System	04 Sep 2020 23:19:00
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 23:19:00

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776255

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776256

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 4'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776257

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:08', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered 'None (1)'	System	06 Sep 2020 03:08:19

FDA-CBER-2022-1614-0776258

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered 'No (N)'	System	06 Sep 2020 03:08:19

FDA-CBER-2022-1614-0776259

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:12', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered 'No (N)'	System	06 Sep 2020 03:08:19

FDA-CBER-2022-1614-0776260

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered 'None (1)'	System	06 Sep 2020 03:08:19

FDA-CBER-2022-1614-0776261

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:18', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'bf732b74-759a-4b0f-b4fb-cbeb3504ff08'	System	06 Sep 2020 03:08:19
User entered '05 Sep 2020 22:08'	System	06 Sep 2020 03:08:19

FDA-CBER-2022-1614-0776262

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776263

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776264

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 5'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776265

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered 'None (1)'	System	06 Sep 2020 23:38:57

FDA-CBER-2022-1614-0776266

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:49', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered 'No (N)'	System	06 Sep 2020 23:38:57

FDA-CBER-2022-1614-0776267

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered 'No (N)'	System	06 Sep 2020 23:38:57

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US3322199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:07:17

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:52', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered 'None (1)'	System	06 Sep 2020 23:38:57

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:38:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3885e542-023b-417f-b0e1-aab67cc8e1c8'	System	06 Sep 2020 23:38:57
User entered '06 Sep 2020 18:38'	System	06 Sep 2020 23:38:57

FDA-CBER-2022-1614-0776270

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776271

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776272

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 6'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776273

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d'	System	08 Sep 2020 00:02:36
User entered 'None (1)'	System	08 Sep 2020 00:02:36

FDA-CBER-2022-1614-0776274

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d'	System	08 Sep 2020 00:02:36
User entered 'No (N)'	System	08 Sep 2020 00:02:36

FDA-CBER-2022-1614-0776275

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:27', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d'	System	08 Sep 2020 00:02:36
User entered 'No (N)'	System	08 Sep 2020 00:02:36

FDA-CBER-2022-1614-0776276

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d'	System	08 Sep 2020 00:02:36
User entered 'None (1)'	System	08 Sep 2020 00:02:36

FDA-CBER-2022-1614-0776277

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3990e4db-50a7-457d-bfb9-b2e0abbe2f1d'	System	08 Sep 2020 00:02:36
User entered '07 Sep 2020 19:02'	System	08 Sep 2020 00:02:36

FDA-CBER-2022-1614-0776278

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776279

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776280

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 7'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776281

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:18', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered 'None (1)'	System	08 Sep 2020 23:31:29

FDA-CBER-2022-1614-0776282

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered 'No (N)'	System	08 Sep 2020 23:31:29

FDA-CBER-2022-1614-0776283

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered 'No (N)'	System	08 Sep 2020 23:31:29

FDA-CBER-2022-1614-0776284

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered 'None (1)'	System	08 Sep 2020 23:31:29

FDA-CBER-2022-1614-0776285

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:27', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'c7d836bd-1a44-4a5a-8aa3-42d2f5ecb2c5'	System	08 Sep 2020 23:31:29
User entered '08 Sep 2020 18:31'	System	08 Sep 2020 23:31:29

FDA-CBER-2022-1614-0776286

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776287

US3322199
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776288

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776289

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

FDA-CBER-2022-1614-0776290

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

FDA-CBER-2022-1614-0776291

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

FDA-CBER-2022-1614-0776292

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

FDA-CBER-2022-1614-0776293

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

FDA-CBER-2022-1614-0776294

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'None (0)'	System	02 Sep 2020 22:22:47

FDA-CBER-2022-1614-0776295

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered 'No (N)'	System	02 Sep 2020 22:22:47

FDA-CBER-2022-1614-0776296

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T17:22:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'd3d00634-a097-4bd3-a1ad-5b354eb289ea'	System	02 Sep 2020 22:22:47
User entered '02 Sep 2020 17:22'	System	02 Sep 2020 22:22:47

FDA-CBER-2022-1614-0776297

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 17:02'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776298

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 19:32'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776299

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776300

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:24', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:30', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:41', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

FDA-CBER-2022-1614-0776305

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:44', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'None (0)'	System	03 Sep 2020 03:14:57

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered 'No (N)'	System	03 Sep 2020 03:14:57

FDA-CBER-2022-1614-0776307

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-02T22:14:54', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a63ba180-2098-45c2-b227-c01b7e05d98d'	System	03 Sep 2020 03:14:57
User entered '02 Sep 2020 22:14'	System	03 Sep 2020 03:14:57

FDA-CBER-2022-1614-0776308

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Sep 2020 20:27'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776309

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776310

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 2'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776311

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:31:57', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

FDA-CBER-2022-1614-0776312

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

FDA-CBER-2022-1614-0776313

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:05', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

FDA-CBER-2022-1614-0776314

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:09', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

FDA-CBER-2022-1614-0776315

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

FDA-CBER-2022-1614-0776316

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'None (0)'	System	04 Sep 2020 04:32:37

FDA-CBER-2022-1614-0776317

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered 'No (N)'	System	04 Sep 2020 04:32:37

FDA-CBER-2022-1614-0776318

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-03T23:32:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '52f66b86-545e-4a6b-9643-af6de64b4c24'	System	04 Sep 2020 04:32:37
User entered '03 Sep 2020 23:32'	System	04 Sep 2020 04:32:37

FDA-CBER-2022-1614-0776319

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776320

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776321

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 3'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776322

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

FDA-CBER-2022-1614-0776323

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:03', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

FDA-CBER-2022-1614-0776324

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:05', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

FDA-CBER-2022-1614-0776325

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:08', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

FDA-CBER-2022-1614-0776326

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

FDA-CBER-2022-1614-0776327

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:12', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'None (0)'	System	04 Sep 2020 23:19:26

FDA-CBER-2022-1614-0776328

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:18', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered 'No (N)'	System	04 Sep 2020 23:19:26

FDA-CBER-2022-1614-0776329

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-04T18:19:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '154dc702-a5c7-4811-9db8-c9b99cf3d48f'	System	04 Sep 2020 23:19:26
User entered '04 Sep 2020 18:19'	System	04 Sep 2020 23:19:26

FDA-CBER-2022-1614-0776330

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776331

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776332

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 4'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776333

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

FDA-CBER-2022-1614-0776335

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

FDA-CBER-2022-1614-0776336

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:27', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

FDA-CBER-2022-1614-0776338

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:30', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'None (0)'	System	06 Sep 2020 03:08:40

FDA-CBER-2022-1614-0776339

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered 'No (N)'	System	06 Sep 2020 03:08:40

FDA-CBER-2022-1614-0776340

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-05T22:08:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '5ff89b52-6aa6-4282-a9b1-4ad2d2c67f40'	System	06 Sep 2020 03:08:40
User entered '05 Sep 2020 22:08'	System	06 Sep 2020 03:08:40

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776342

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776343

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 5'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776344

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

FDA-CBER-2022-1614-0776345

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

FDA-CBER-2022-1614-0776346

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:07', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

FDA-CBER-2022-1614-0776347

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

FDA-CBER-2022-1614-0776348

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

FDA-CBER-2022-1614-0776349

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'None (0)'	System	06 Sep 2020 23:39:29

FDA-CBER-2022-1614-0776350

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered 'No (N)'	System	06 Sep 2020 23:39:29

FDA-CBER-2022-1614-0776351

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-06T18:39:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f5a8f5fe-3c42-40ec-8fab-11ec86c103b0'	System	06 Sep 2020 23:39:29
User entered '06 Sep 2020 18:39'	System	06 Sep 2020 23:39:29

FDA-CBER-2022-1614-0776352

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776353

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776354

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 6'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776355

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

FDA-CBER-2022-1614-0776356

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

FDA-CBER-2022-1614-0776357

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

FDA-CBER-2022-1614-0776358

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

FDA-CBER-2022-1614-0776359

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

FDA-CBER-2022-1614-0776360

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'None (0)'	System	08 Sep 2020 00:02:51

FDA-CBER-2022-1614-0776361

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:45', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered 'No (N)'	System	08 Sep 2020 00:02:51

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-07T19:02:47', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0225311b-8f6d-4af6-9e1d-7d3ab0ab370d'	System	08 Sep 2020 00:02:51
User entered '07 Sep 2020 19:02'	System	08 Sep 2020 00:02:51

FDA-CBER-2022-1614-0776363

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776364

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776365

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 7'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776366

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

FDA-CBER-2022-1614-0776368

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

FDA-CBER-2022-1614-0776369

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:35', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

FDA-CBER-2022-1614-0776370

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

FDA-CBER-2022-1614-0776371

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'None (0)'	System	08 Sep 2020 23:31:48

FDA-CBER-2022-1614-0776372

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered 'No (N)'	System	08 Sep 2020 23:31:48

FDA-CBER-2022-1614-0776373

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-09-08T18:31:45', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '3cab9645-bb30-4e88-b2b1-2a823d4971ac'	System	08 Sep 2020 23:31:48
User entered '08 Sep 2020 18:31'	System	08 Sep 2020 23:31:48

FDA-CBER-2022-1614-0776374

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776375

US3322199
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776376

US3322199
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:34

FDA-CBER-2022-1614-0776377

US3322199
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '9 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:34

FDA-CBER-2022-1614-0776378

US3322199
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:34

FDA-CBER-2022-1614-0776379

US3322199
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:34

FDA-CBER-2022-1614-0776380

US3322199
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 17:53:39

FDA-CBER-2022-1614-0776381

US3322199
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User entered '1'	System	14 Sep 2020 17:53:39

FDA-CBER-2022-1614-0776382

US3322199
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:14

FDA-CBER-2022-1614-0776383

US3322199
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '16 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:14

FDA-CBER-2022-1614-0776384

US3322199
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:14

FDA-CBER-2022-1614-0776385

US3322199
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:14

FDA-CBER-2022-1614-0776386

US3322199
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 18:51:19

US3322199
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User entered '1'	System	16 Sep 2020 18:51:19

FDA-CBER-2022-1614-0776388

US3322199
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:32

FDA-CBER-2022-1614-0776389

US3322199
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '23 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:32

FDA-CBER-2022-1614-0776390

US3322199
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:32

FDA-CBER-2022-1614-0776391

US3322199
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:32

FDA-CBER-2022-1614-0776392

US3322199
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:17:37

US3322199
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:02:16
User entered '1'	System	25 Sep 2020 16:17:37

FDA-CBER-2022-1614-0776394

US3322199
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:05:49

FDA-CBER-2022-1614-0776395

US3322199
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:05:49

FDA-CBER-2022-1614-0776396

US3322199
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
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 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Oct 2020 22:05:49

FDA-CBER-2022-1614-0776397

US3322199
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'VISIT2'	System	01 Oct 2020 22:05:49

FDA-CBER-2022-1614-0776398

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User accepted default value 'Pre-Dose (PREDOSE)'		01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776399

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776400

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776401

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '11:15'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776402

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1 Oct 2020 11:15'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776403

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '98.1' F	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776404

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776405

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776406

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '60'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776407

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'bpm'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776408

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '17'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776409

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'breaths/min'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776410

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '117'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776411

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'mmHg'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776412

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '76'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776413

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'mmHg'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776414

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User accepted default value 'Post-Dose (POSTDOSE)'		01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776415

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776416

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776417

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '12:24'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776418

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1 Oct 2020 12:24'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776419

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '98.2' F	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776420

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776421

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776422

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '60'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776423

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'bpm'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776424

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '17'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776425

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'breaths/min'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776426

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '116'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776427

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'mmHg'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776428

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '84'	(b) (4), (b) (6)	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776429

US3322199
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'mmHg'	System	01 Oct 2020 22:07:58

FDA-CBER-2022-1614-0776430

US3322199
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:07:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:08:04

FDA-CBER-2022-1614-0776431

US3322199
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:07:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:08:04

FDA-CBER-2022-1614-0776432

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776433

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776434

US3322199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:17

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 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776436

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1 Oct 2020'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776437

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '11:52'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776438

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1 Oct 2020 11:52'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776439

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776440

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'ONCE'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776441

US3322199
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:07:17
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776442

US3322199
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:09:48

FDA-CBER-2022-1614-0776443

US3322199
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:09:48

FDA-CBER-2022-1614-0776444

US3322199
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '11:40'	(b) (4), (b) (6)	01 Oct 2020 22:09:48

FDA-CBER-2022-1614-0776445

US3322199
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1 Oct 2020 11:40'	System	01 Oct 2020 22:09:48

FDA-CBER-2022-1614-0776446

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:07:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776447

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:07:17
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776448

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:07:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776449

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:07:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '11:35'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776450

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:07:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1 Oct 2020 11:35'	System	01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776451

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:07:17
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776452

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:07:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776453

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:07:17
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776454

US3322199
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:07:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered empty.	System	01 Oct 2020 22:10:15

FDA-CBER-2022-1614-0776455

US3322199
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:10:18

FDA-CBER-2022-1614-0776456

US3322199
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	01 Oct 2020 22:10:18

FDA-CBER-2022-1614-0776457

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776458

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '9cfefe46-eef0-464a-8734-ea299231bd83'	System	01 Oct 2020 17:28:33
User entered 'Yes (Y)'	System	01 Oct 2020 17:28:33

FDA-CBER-2022-1614-0776459

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:18', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '9cfefe46-eef0-464a-8734-ea299231bd83'	System	01 Oct 2020 17:28:33
User entered '98.2'	System	01 Oct 2020 17:28:33

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:24', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '9cfefe46-eef0-464a-8734-ea299231bd83'	System	01 Oct 2020 17:28:33
User entered 'No (N)'	System	01 Oct 2020 17:28:33

FDA-CBER-2022-1614-0776461

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:28', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '9cfefe46-eef0-464a-8734-ea299231bd83'	System	01 Oct 2020 17:28:33
User entered '01 Oct 2020 12:28'	System	01 Oct 2020 17:28:33

FDA-CBER-2022-1614-0776462

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 12:12'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776463

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 14:42'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776464

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776465

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:01:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c9fbb85-7e1f-4e3c-b0d5-38aa5d6c3b1e'	System	02 Oct 2020 00:02:37
User entered 'Yes (Y)'	System	02 Oct 2020 00:02:37

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:01:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c9fbb85-7e1f-4e3c-b0d5-38aa5d6c3b1e'	System	02 Oct 2020 00:02:37
User entered '98.1'	System	02 Oct 2020 00:02:37

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:14', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c9fbb85-7e1f-4e3c-b0d5-38aa5d6c3b1e'	System	02 Oct 2020 00:02:37
User entered 'No (N)'	System	02 Oct 2020 00:02:37

FDA-CBER-2022-1614-0776468

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c9fbb85-7e1f-4e3c-b0d5-38aa5d6c3b1e'	System	02 Oct 2020 00:02:37
User entered '01 Oct 2020 19:02'	System	02 Oct 2020 00:02:37

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 15:37'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776470

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776471

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 2'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776472

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:00:59', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '09ed7e9e-fe02-4589-ad48-38d28af6ce97'	System	03 Oct 2020 00:01:16
User entered 'Yes (Y)'	System	03 Oct 2020 00:01:16

FDA-CBER-2022-1614-0776473

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '09ed7e9e-fe02-4589-ad48-38d28af6ce97'	System	03 Oct 2020 00:01:16
User entered '97.8'	System	03 Oct 2020 00:01:16

FDA-CBER-2022-1614-0776474

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:09', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '09ed7e9e-fe02-4589-ad48-38d28af6ce97'	System	03 Oct 2020 00:01:16
User entered 'No (N)'	System	03 Oct 2020 00:01:16

FDA-CBER-2022-1614-0776475

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:14', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '09ed7e9e-fe02-4589-ad48-38d28af6ce97'	System	03 Oct 2020 00:01:16
User entered '02 Oct 2020 19:01'	System	03 Oct 2020 00:01:16

FDA-CBER-2022-1614-0776476

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776477

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776478

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 3'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776479

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ee34ab17-f5aa-4516-83c8-6555ffa564de'	System	04 Oct 2020 00:43:29
User entered 'Yes (Y)'	System	04 Oct 2020 00:43:29

FDA-CBER-2022-1614-0776480

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ee34ab17-f5aa-4516-83c8-6555ffa564de'	System	04 Oct 2020 00:43:29
User entered '98.2'	System	04 Oct 2020 00:43:29

FDA-CBER-2022-1614-0776481

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ee34ab17-f5aa-4516-83c8-6555ffa564de'	System	04 Oct 2020 00:43:29
User entered 'No (N)'	System	04 Oct 2020 00:43:29

FDA-CBER-2022-1614-0776482

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ee34ab17-f5aa-4516-83c8-6555ffa564de'	System	04 Oct 2020 00:43:29
User entered '03 Oct 2020 19:43'	System	04 Oct 2020 00:43:29

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776484

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776485

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 4'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776486

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b5d9c3a4-9945-4731-aad9-a9b6042f7115'	System	05 Oct 2020 01:32:44
User entered 'Yes (Y)'	System	05 Oct 2020 01:32:44

FDA-CBER-2022-1614-0776487

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b5d9c3a4-9945-4731-aad9-a9b6042f7115'	System	05 Oct 2020 01:32:44
User entered '98.3'	System	05 Oct 2020 01:32:44

FDA-CBER-2022-1614-0776488

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b5d9c3a4-9945-4731-aad9-a9b6042f7115'	System	05 Oct 2020 01:32:44
User entered 'No (N)'	System	05 Oct 2020 01:32:44

FDA-CBER-2022-1614-0776489

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:41', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b5d9c3a4-9945-4731-aad9-a9b6042f7115'	System	05 Oct 2020 01:32:44
User entered '04 Oct 2020 20:32'	System	05 Oct 2020 01:32:44

FDA-CBER-2022-1614-0776490

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776491

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776492

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 5'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776493

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:00:47', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '00d8778b-7045-4c86-bcb8-6a55d0d0a32a'	System	06 Oct 2020 00:01:16
User entered 'Yes (Y)'	System	06 Oct 2020 00:01:16

FDA-CBER-2022-1614-0776494

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:03', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '00d8778b-7045-4c86-bcb8-6a55d0d0a32a'	System	06 Oct 2020 00:01:16
User entered '97.8'	System	06 Oct 2020 00:01:16

FDA-CBER-2022-1614-0776495

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '00d8778b-7045-4c86-bcb8-6a55d0d0a32a'	System	06 Oct 2020 00:01:16
User entered 'No (N)'	System	06 Oct 2020 00:01:16

FDA-CBER-2022-1614-0776496

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '00d8778b-7045-4c86-bcb8-6a55d0d0a32a'	System	06 Oct 2020 00:01:16
User entered '05 Oct 2020 19:01'	System	06 Oct 2020 00:01:16

FDA-CBER-2022-1614-0776497

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776498

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776499

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 6'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776500

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:01:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '39f5c307-231b-4981-9b04-3941d943a6b8'	System	07 Oct 2020 00:02:01
User entered 'Yes (Y)'	System	07 Oct 2020 00:02:01

FDA-CBER-2022-1614-0776501

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:01:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '39f5c307-231b-4981-9b04-3941d943a6b8'	System	07 Oct 2020 00:02:01
User entered '98.4'	System	07 Oct 2020 00:02:01

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:01:54', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '39f5c307-231b-4981-9b04-3941d943a6b8'	System	07 Oct 2020 00:02:01
User entered 'No (N)'	System	07 Oct 2020 00:02:01

FDA-CBER-2022-1614-0776503

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:01:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '39f5c307-231b-4981-9b04-3941d943a6b8'	System	07 Oct 2020 00:02:01
User entered '06 Oct 2020 19:01'	System	07 Oct 2020 00:02:01

FDA-CBER-2022-1614-0776504

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776505

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776506

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 7'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776507

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f8eda7f4-daa4-4ace-b204-cc9901614c82'	System	08 Oct 2020 00:48:48
User entered 'Yes (Y)'	System	08 Oct 2020 00:48:48

FDA-CBER-2022-1614-0776508

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f8eda7f4-daa4-4ace-b204-cc9901614c82'	System	08 Oct 2020 00:48:48
User entered '98.1'	System	08 Oct 2020 00:48:48

FDA-CBER-2022-1614-0776509

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f8eda7f4-daa4-4ace-b204-cc9901614c82'	System	08 Oct 2020 00:48:48
User entered 'No (N)'	System	08 Oct 2020 00:48:48

FDA-CBER-2022-1614-0776510

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'f8eda7f4-daa4-4ace-b204-cc9901614c82'	System	08 Oct 2020 00:48:48
User entered '07 Oct 2020 19:48'	System	08 Oct 2020 00:48:48

FDA-CBER-2022-1614-0776511

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776512

US3322199
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776513

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776514

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:34', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e'	System	01 Oct 2020 17:28:48
User entered 'None (1)'	System	01 Oct 2020 17:28:48

FDA-CBER-2022-1614-0776515

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e'	System	01 Oct 2020 17:28:48
User entered 'No (N)'	System	01 Oct 2020 17:28:48

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e'	System	01 Oct 2020 17:28:48
User entered 'No (N)'	System	01 Oct 2020 17:28:48

FDA-CBER-2022-1614-0776517

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e'	System	01 Oct 2020 17:28:48
User entered 'None (1)'	System	01 Oct 2020 17:28:48

FDA-CBER-2022-1614-0776518

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '728570f1-7970-4cc5-b740-9d02c8ac461e'	System	01 Oct 2020 17:28:48
User entered '01 Oct 2020 12:28'	System	01 Oct 2020 17:28:48

FDA-CBER-2022-1614-0776519

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 12:12'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776520

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 14:42'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776521

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776522

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered 'None (1)'	System	02 Oct 2020 00:03:28

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:39', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered 'No (N)'	System	02 Oct 2020 00:03:28

FDA-CBER-2022-1614-0776524

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered 'No (N)'	System	02 Oct 2020 00:03:28

FDA-CBER-2022-1614-0776525

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:02:54', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered 'None (1)'	System	02 Oct 2020 00:03:28

FDA-CBER-2022-1614-0776526

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '24f98c3a-9eeb-43b6-a20f-092d66313d03'	System	02 Oct 2020 00:03:28
User entered '01 Oct 2020 19:03'	System	02 Oct 2020 00:03:28

FDA-CBER-2022-1614-0776527

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 15:37'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776528

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776529

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 2'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776530

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:17', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered 'None (1)'	System	03 Oct 2020 00:01:30

FDA-CBER-2022-1614-0776531

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:20', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered 'No (N)'	System	03 Oct 2020 00:01:30

FDA-CBER-2022-1614-0776532

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered 'No (N)'	System	03 Oct 2020 00:01:30

FDA-CBER-2022-1614-0776533

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:23', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered 'None (1)'	System	03 Oct 2020 00:01:30

FDA-CBER-2022-1614-0776534

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:25', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6c2125d5-b794-4046-8aba-4fb388fe0ca8'	System	03 Oct 2020 00:01:30
User entered '02 Oct 2020 19:01'	System	03 Oct 2020 00:01:30

FDA-CBER-2022-1614-0776535

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776536

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776537

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 3'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776538

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered 'None (1)'	System	04 Oct 2020 00:43:40

FDA-CBER-2022-1614-0776539

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered 'No (N)'	System	04 Oct 2020 00:43:40

FDA-CBER-2022-1614-0776540

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered 'No (N)'	System	04 Oct 2020 00:43:40

FDA-CBER-2022-1614-0776541

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:35', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered 'None (1)'	System	04 Oct 2020 00:43:40

FDA-CBER-2022-1614-0776542

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:37', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '84422dca-1e40-46f0-b2e9-69bbcd917787'	System	04 Oct 2020 00:43:40
User entered '03 Oct 2020 19:43'	System	04 Oct 2020 00:43:40

FDA-CBER-2022-1614-0776543

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776544

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776545

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 4'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776546

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:44', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered 'None (1)'	System	05 Oct 2020 01:32:52

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered 'No (N)'	System	05 Oct 2020 01:32:52

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:47', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered 'No (N)'	System	05 Oct 2020 01:32:52

FDA-CBER-2022-1614-0776549

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:49', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered 'None (1)'	System	05 Oct 2020 01:32:52

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '984fff7e-6f49-4709-b060-16035ef4f1f5'	System	05 Oct 2020 01:32:52
User entered '04 Oct 2020 20:32'	System	05 Oct 2020 01:32:52

FDA-CBER-2022-1614-0776551

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776552

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776553

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 5'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776554

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:17', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f'	System	06 Oct 2020 00:01:27
User entered 'None (1)'	System	06 Oct 2020 00:01:27

FDA-CBER-2022-1614-0776555

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f'	System	06 Oct 2020 00:01:27
User entered 'No (N)'	System	06 Oct 2020 00:01:27

FDA-CBER-2022-1614-0776556

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:20', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f'	System	06 Oct 2020 00:01:27
User entered 'No (N)'	System	06 Oct 2020 00:01:27

FDA-CBER-2022-1614-0776557

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f'	System	06 Oct 2020 00:01:27
User entered 'None (1)'	System	06 Oct 2020 00:01:27

FDA-CBER-2022-1614-0776558

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:24', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'a6315770-ca19-453f-bdb4-2c0b8acafd3f'	System	06 Oct 2020 00:01:27
User entered '05 Oct 2020 19:01'	System	06 Oct 2020 00:01:27

FDA-CBER-2022-1614-0776559

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776560

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776561

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 6'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776562

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered 'None (1)'	System	07 Oct 2020 00:02:13

FDA-CBER-2022-1614-0776563

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:04', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered 'No (N)'	System	07 Oct 2020 00:02:13

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered 'No (N)'	System	07 Oct 2020 00:02:13

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:08', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered 'None (1)'	System	07 Oct 2020 00:02:13

FDA-CBER-2022-1614-0776566

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:11', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'af66dd5d-8111-4ce1-a6f7-1ea6e6595148'	System	07 Oct 2020 00:02:13
User entered '06 Oct 2020 19:02'	System	07 Oct 2020 00:02:13

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776568

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776569

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 7'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776570

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered 'None (1)'	System	08 Oct 2020 00:49:05

FDA-CBER-2022-1614-0776571

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered 'No (N)'	System	08 Oct 2020 00:49:05

FDA-CBER-2022-1614-0776572

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered 'No (N)'	System	08 Oct 2020 00:49:05

FDA-CBER-2022-1614-0776573

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:48:59', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered 'None (1)'	System	08 Oct 2020 00:49:05

FDA-CBER-2022-1614-0776574

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '65dc8d19-8c13-4737-a65b-40de9f6c0c42'	System	08 Oct 2020 00:49:05
User entered '07 Oct 2020 19:49'	System	08 Oct 2020 00:49:05

FDA-CBER-2022-1614-0776575

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776576

US3322199
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776577

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776578

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:49', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

FDA-CBER-2022-1614-0776579

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:51', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

FDA-CBER-2022-1614-0776580

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:54', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

FDA-CBER-2022-1614-0776581

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

FDA-CBER-2022-1614-0776582

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:28:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

FDA-CBER-2022-1614-0776583

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:29:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'None (0)'	System	01 Oct 2020 17:29:33

FDA-CBER-2022-1614-0776584

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:29:02', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered 'No (N)'	System	01 Oct 2020 17:29:33

FDA-CBER-2022-1614-0776585

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T12:29:04', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0b41b47d-cc9c-4329-99da-44d3475ff7ad'	System	01 Oct 2020 17:29:33
User entered '01 Oct 2020 12:29'	System	01 Oct 2020 17:29:33

FDA-CBER-2022-1614-0776586

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 12:12'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776587

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 14:42'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776588

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776589

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:46', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

FDA-CBER-2022-1614-0776591

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:52', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:03:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

FDA-CBER-2022-1614-0776593

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:04:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

FDA-CBER-2022-1614-0776594

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:04:03', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'None (0)'	System	02 Oct 2020 00:04:12

FDA-CBER-2022-1614-0776595

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:04:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered 'No (N)'	System	02 Oct 2020 00:04:12

FDA-CBER-2022-1614-0776596

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-01T19:04:09', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '626bf86a-ea7a-4aa9-8f95-cefe91dba7a4'	System	02 Oct 2020 00:04:12
User entered '01 Oct 2020 19:04'	System	02 Oct 2020 00:04:12

FDA-CBER-2022-1614-0776597

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '01 Oct 2020 15:37'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776598

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776599

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 2'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776600

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

FDA-CBER-2022-1614-0776601

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

FDA-CBER-2022-1614-0776602

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

FDA-CBER-2022-1614-0776603

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:33', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

FDA-CBER-2022-1614-0776604

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:35', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

FDA-CBER-2022-1614-0776605

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'None (0)'	System	03 Oct 2020 00:01:43

FDA-CBER-2022-1614-0776606

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered 'No (N)'	System	03 Oct 2020 00:01:43

FDA-CBER-2022-1614-0776607

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-02T19:01:41', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '42c833d6-62ef-4b37-b65e-976b7d3fad66'	System	03 Oct 2020 00:01:43
User entered '02 Oct 2020 19:01'	System	03 Oct 2020 00:01:43

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776609

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776610

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 3'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776611

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

FDA-CBER-2022-1614-0776612

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

FDA-CBER-2022-1614-0776613

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

FDA-CBER-2022-1614-0776614

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

FDA-CBER-2022-1614-0776615

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:52', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

FDA-CBER-2022-1614-0776616

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'None (0)'	System	04 Oct 2020 00:44:02

FDA-CBER-2022-1614-0776617

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:43:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered 'No (N)'	System	04 Oct 2020 00:44:02

FDA-CBER-2022-1614-0776618

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-03T19:44:00', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '0154ce48-203c-4b74-b3c5-762bbd7cbce7'	System	04 Oct 2020 00:44:02
User entered '03 Oct 2020 19:44'	System	04 Oct 2020 00:44:02

FDA-CBER-2022-1614-0776619

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776620

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776621

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 4'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776622

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:53', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

FDA-CBER-2022-1614-0776623

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:55', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

FDA-CBER-2022-1614-0776624

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:56', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

FDA-CBER-2022-1614-0776625

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:57', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

FDA-CBER-2022-1614-0776626

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:58', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

FDA-CBER-2022-1614-0776627

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:32:59', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'None (0)'	System	05 Oct 2020 01:33:05

FDA-CBER-2022-1614-0776628

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:33:01', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered 'No (N)'	System	05 Oct 2020 01:33:05

FDA-CBER-2022-1614-0776629

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-04T20:33:03', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'b14705f4-a619-4d5d-8f6d-0763302d2ae7'	System	05 Oct 2020 01:33:05
User entered '04 Oct 2020 20:33'	System	05 Oct 2020 01:33:05

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776631

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776632

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 5'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776633

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:36', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

FDA-CBER-2022-1614-0776634

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:38', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:40', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

FDA-CBER-2022-1614-0776636

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:42', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:43', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

FDA-CBER-2022-1614-0776638

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:45', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'None (0)'	System	06 Oct 2020 00:01:53

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:47', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered 'No (N)'	System	06 Oct 2020 00:01:53

FDA-CBER-2022-1614-0776640

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-05T19:01:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: 'ccd077ed-5d21-4121-bd4b-bdeef7b35bf9'	System	06 Oct 2020 00:01:53
User entered '05 Oct 2020 19:01'	System	06 Oct 2020 00:01:53

FDA-CBER-2022-1614-0776641

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776642

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776643

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 6'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776644

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

FDA-CBER-2022-1614-0776645

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:17', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

FDA-CBER-2022-1614-0776646

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:20', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

FDA-CBER-2022-1614-0776647

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:22', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

FDA-CBER-2022-1614-0776648

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:24', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

FDA-CBER-2022-1614-0776649

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:26', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'None (0)'	System	07 Oct 2020 00:02:34

FDA-CBER-2022-1614-0776650

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:29', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered 'No (N)'	System	07 Oct 2020 00:02:34

FDA-CBER-2022-1614-0776651

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-06T19:02:31', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '7838e167-d690-478d-9997-3edd27d2c537'	System	07 Oct 2020 00:02:34
User entered '06 Oct 2020 19:02'	System	07 Oct 2020 00:02:34

FDA-CBER-2022-1614-0776652

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776653

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776654

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	01 Oct 2020 16:58:12
User entered 'Day 7'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776655

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:05', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

FDA-CBER-2022-1614-0776656

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:06', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

FDA-CBER-2022-1614-0776657

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:08', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

FDA-CBER-2022-1614-0776658

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:09', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

FDA-CBER-2022-1614-0776659

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:10', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

FDA-CBER-2022-1614-0776660

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:13', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'None (0)'	System	08 Oct 2020 00:49:24

FDA-CBER-2022-1614-0776661

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:15', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered 'No (N)'	System	08 Oct 2020 00:49:24

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-10-07T19:49:19', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '6afa5668-5c2b-4e40-8c66-28503e22ffce'	System	08 Oct 2020 00:49:24
User entered '07 Oct 2020 19:49'	System	08 Oct 2020 00:49:24

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776664

US3322199
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:07:17
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:58:12

FDA-CBER-2022-1614-0776665

US3322199
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:25

FDA-CBER-2022-1614-0776666

US3322199
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 06:31:49
User entered '13 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 15:04:12
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'multiple unsuccessful attempts made and left unanswered' (Site from System).	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:42
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Oct 2020 14:27:25
User entered '12 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:25

FDA-CBER-2022-1614-0776667

US3322199
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 15:04:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:25

FDA-CBER-2022-1614-0776668

US3322199
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'MULTIPLE UNSUCCESSFUL ATTEMPTS, patient finally responded on 13-Oct-2020, out of window' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 15:04:12
User entered 'multiple unsuccessful attempts'	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:25

FDA-CBER-2022-1614-0776669

US3322199
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Oct 2020 14:27:49

FDA-CBER-2022-1614-0776670

US3322199
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	13 Oct 2020 14:27:49

FDA-CBER-2022-1614-0776671

US3322199
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:45:30

FDA-CBER-2022-1614-0776672

US3322199
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '15 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:45:30

FDA-CBER-2022-1614-0776673

US3322199
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:45:30

FDA-CBER-2022-1614-0776674

US3322199
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:45:30

FDA-CBER-2022-1614-0776675

US3322199
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 13:47:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 13:47:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:47:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 13:46:57
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 13:46:57

FDA-CBER-2022-1614-0776676

US3322199
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	16 Oct 2020 13:47:03
User entered empty.	System	16 Oct 2020 13:46:57

FDA-CBER-2022-1614-0776677

US3322199
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:45

FDA-CBER-2022-1614-0776678

US3322199
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '22 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:45

FDA-CBER-2022-1614-0776679

US3322199
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:45

FDA-CBER-2022-1614-0776680

US3322199
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:07:17
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:45

FDA-CBER-2022-1614-0776681

US3322199
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:30:49

FDA-CBER-2022-1614-0776682

US3322199
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	22 Oct 2020 17:30:49

FDA-CBER-2022-1614-0776683

US3322199
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:41:55

FDA-CBER-2022-1614-0776684

US3322199
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:41:55

FDA-CBER-2022-1614-0776685

US3322199
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
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 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Oct 2020 20:41:55

FDA-CBER-2022-1614-0776686

US3322199
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:07:17
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'VISIT3'	System	30 Oct 2020 20:41:55

FDA-CBER-2022-1614-0776687

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776688

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776689

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '11:19'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776690

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '30 Oct 2020 11:19'	System	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776691

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '96.8' F	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776692

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776693

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776694

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '47'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776695

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'bpm'	System	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776696

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '14'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776697

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'breaths/min'	System	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776698

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '129'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776699

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'mmHg'	System	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776700

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '62'	(b) (4), (b) (6)	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776701

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered 'mmHg'	System	30 Oct 2020 20:42:48

FDA-CBER-2022-1614-0776702

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01

FDA-CBER-2022-1614-0776703

US3322199
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:07:17
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01

FDA-CBER-2022-1614-0776704

US3322199
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:07:17
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:42:59

FDA-CBER-2022-1614-0776705

US3322199
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:07:17
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:42:59

FDA-CBER-2022-1614-0776706

US3322199
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:43:09

FDA-CBER-2022-1614-0776707

US3322199
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:43:09

FDA-CBER-2022-1614-0776708

US3322199
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '11:45'	(b) (4), (b) (6)	30 Oct 2020 20:43:09

FDA-CBER-2022-1614-0776709

US3322199
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:07:17
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '30 Oct 2020 11:45'	System	30 Oct 2020 20:43:09

FDA-CBER-2022-1614-0776710

US3322199
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:43:15

FDA-CBER-2022-1614-0776711

US3322199
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:07:17
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	30 Oct 2020 20:43:15

FDA-CBER-2022-1614-0776712

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 64'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776713

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-11-02T15:48:21', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '76907bee-397c-42ce-89f9-24eeb62af045'	System	02 Nov 2020 21:48:54
User entered 'No (N)'	System	02 Nov 2020 21:48:54

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-11-02T15:48:32', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '76907bee-397c-42ce-89f9-24eeb62af045'	System	02 Nov 2020 21:48:54
User entered 'No (N)'	System	02 Nov 2020 21:48:54

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6D4BFB6-9037-4C89-8EF5-C24537EBA4F1)', Time: '2020-11-02T15:48:50', User OID: 'PatientReportedOutcome (US3322199)', ODM File OID: '76907bee-397c-42ce-89f9-24eeb62af045'	System	02 Nov 2020 21:48:54
User entered '02 Nov 2020 15:48:50'	System	02 Nov 2020 21:48:54

FDA-CBER-2022-1614-0776716

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776717

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:20:00
Data entry locked.	System	02 Sep 2020 21:48:04
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776718

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 71'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776719

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776724

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776725

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776726

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776727

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776728

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776729

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776730

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776731

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776732

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776733

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776734

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776735

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776736

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776737

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776738

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776739

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776740

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776744

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27
Data entry locked.	System	02 Sep 2020 21:48:04
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776745

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27
Data entry locked.	System	02 Sep 2020 21:48:04
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776746

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27
Data entry locked.	System	02 Sep 2020 21:48:04
User entered 'Day 78'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776747

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776752

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776753

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776754

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776755

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776756

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776757

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776758

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776759

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776760

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776761

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776762

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776763

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776764

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776765

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776766

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776767

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776768

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27

FDA-CBER-2022-1614-0776772

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27
Data entry locked.	System	02 Sep 2020 21:48:04
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776773

US3322199
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:07:17
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:58:27
Data entry locked.	System	02 Sep 2020 21:48:04
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 21:48:04

FDA-CBER-2022-1614-0776774

US3322199
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 17:07:17
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:12
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:12:12

FDA-CBER-2022-1614-0776775

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 23:35:24
User entered 'USA-US060-2020-mRNA-1273-P301000012'	System	23 Nov 2020 23:35:05
User entered 'New'	(b) (4), (b) (6)	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776776

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:52
Data point term sent to Coder	System	21 Nov 2020 00:08:02
Coding entries removed.	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User entered 'Fatal Myocardial Infarction' reason for change: New Information		21 Nov 2020 00:07:53
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:39:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:39:03
Data point term sent to Coder	System	20 Nov 2020 22:38:07
User entered 'myocardial infarction' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:37:16
Data point term sent to Coder	System	20 Nov 2020 22:13:41
User entered 'Massive Heart Attack'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776777

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776778

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776779

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776780

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776781

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776782

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered empty.	System	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776783

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776784

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776785

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776786

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered empty.	System	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776787

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776788

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776789

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776790

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776791

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776792

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776793

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776794

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776796

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776797

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776798

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776799

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776801

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776802

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '1'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776803

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776804

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776805

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Fatal (FATAL)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776806

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

FDA-CBER-2022-1614-0776807

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
User closed query 'PV Query: Please confirm if any additional information regarding the subject's death will be able to be obtained by the site. If none available, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:35:01
Query 'PV Query: Please confirm if any additional information regarding the subject's death will be able to be obtained by the site. If none available, please state so.' answered with 'The family of the patient refuses to release any other details regarding the subject's death. Unfortunately, we have tried all avenues conceivable to us, but we cannot get any more information from the family, including but not limited to which hospital the patient passed away at, so we cannot obtain medical records, details regarding the patient's death, or a death certificate.' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	12 Jan 2021 16:42:44
User opened query 'PV Query: Please confirm if any additional information regarding the subject's death will be able to be obtained by the site. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 12:40:15
User closed query 'PV Query: Please confirm if any additional information regarding the subject's death will be able to be obtained by the site. ' (Site from Safety).		05 Jan 2021 17:03:07
Query 'PV Query: Please confirm if any additional information regarding the subject's death will be able to be obtained by the site. ' answered with 'Site has had multiple unsuccessful attempts to gather more information regarding subject's death. PI will be making additional attempts and site will update accordingly. Until then, information is still pending. ' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	04 Jan 2021 19:13:36
User opened query 'PV Query: Please confirm if any additional information regarding the subject's death will be able to be obtained by the site. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 19:34:14

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 22:41:59
User closed query 'PV Query: Please provide the death certificate, if available. If not available, please state so. Please leave query open until information is available. ' (Site from Safety).		28 Dec 2020 22:41:56
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so. Please leave query open until information is available. ' (Site from Safety).		28 Dec 2020 22:41:49
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. Please leave query open until information is available. ' (Site from Safety).		28 Dec 2020 22:41:45
User closed query 'PV Query: Please state if any resuscitation attempt was done. Please leave query open until information is available. ' (Site from Safety).		28 Dec 2020 22:41:41
User closed query 'PV Query: Did the patient have any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so. Please leave query open until information is available. ' (Site from Safety).		28 Dec 2020 22:41:37
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so. Please leave query open until information is available. ' answered with 'per source multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' Death.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	24 Dec 2020 03:07:04

FDA-CBER-2022-1614-0776809

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the death certificate, if available. If not available, please state so. Please leave query open until information is available. ' answered with 'per source multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' Death.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	24 Dec 2020 03:07:00
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so. Please leave query open until information is available. ' answered with 'per source multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' Death.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	24 Dec 2020 03:06:57
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. Please leave query open until information is available. ' answered with 'per source multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' Death.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	24 Dec 2020 03:06:53
Query 'PV Query: Please state if any resuscitation attempt was done. Please leave query open until information is available. ' answered with 'per source multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' Death.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	24 Dec 2020 03:06:48

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Did the patient have any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so. Please leave query open until information is available. ' answered with 'per source multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' Death.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	24 Dec 2020 03:06:44
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 21:41:53
User opened query 'PV Query: Please provide the death certificate, if available. If not available, please state so. Please leave query open until information is available. ' (Site from Safety).		22 Dec 2020 21:41:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so. Please leave query open until information is available. ' (Site from Safety).		22 Dec 2020 21:41:35
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. Please leave query open until information is available. ' (Site from Safety).		22 Dec 2020 21:41:26
User opened query 'PV Query: Please state if any resuscitation attempt was done. Please leave query open until information is available. ' (Site from Safety).		22 Dec 2020 21:41:18
User opened query 'PV Query: Did the patient have any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so. Please leave query open until information is available. ' (Site from Safety).		22 Dec 2020 21:41:06

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Did the patient had any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 21:47:19
User closed query 'PV Query: Please state if any resuscitation attempt was done?' (Site from Safety).		21 Dec 2020 21:47:14
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).		21 Dec 2020 21:47:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so.' (Site from Safety).		21 Dec 2020 21:47:07
User closed query 'PV Query: Please provide the death certificate, if available. If not available, please state so.' (Site from Safety).		21 Dec 2020 21:47:04
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).		21 Dec 2020 21:47:01
Query 'PV Query: Did the patient had any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so.' answered with 'Multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' SAE. Pending medical records.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:10:48
Query 'PV Query: Please state if any resuscitation attempt was done?' answered with 'Multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' SAE. Pending medical records.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:10:45

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
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 'Multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' SAE. Pending medical records.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:10:41
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so.' answered with 'Multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' SAE. Pending medical records.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:10:35
Query 'PV Query: Please provide the death certificate, if available. If not available, please state so.' answered with 'Multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' SAE. Pending medical records.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:10:29
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'Multiple unsuccessful attempts made to contact with Subject's relatives/Emergency contact to gather more information regarding the Subjects' SAE. Pending medical records.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:10:25
User closed query 'PV Query: Did the patient have any prior heart attacks?' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 22:01:19
Query 'PV Query: Did the patient have any prior heart attacks?' answered with 'none listed in medical history' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	14 Dec 2020 14:24:58
User opened query 'PV Query: Did the patient have any prior heart attacks?' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:22:04

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Did the patient had any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 21:21:32
User opened query 'PV Query: Please state if any resuscitation attempt was done?' (Site from Safety).		11 Dec 2020 21:21:13
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).		11 Dec 2020 21:20:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so.' (Site from Safety).		11 Dec 2020 21:20:32
User opened query 'PV Query: Please provide the death certificate, if available. If not available, please state so.' (Site from Safety).		11 Dec 2020 21:20:18
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).		11 Dec 2020 21:20:00
User closed query 'PV Query: As per the case narrative, the subject had obesity. Please confirm if obesity is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If obesity is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).		08 Dec 2020 17:22:35
Query 'PV Query: As per the case narrative, the subject had obesity. Please confirm if obesity is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If obesity is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'Please see updated MH' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 22:41:14
User closed query 'PV Query: Please state if any resuscitation attempt was done?' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 15:36:37

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Did the patient have any prior heart attacks?' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 15:36:36
User closed query 'PV Query: Did the patient had any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so.' (Site from Safety).		07 Dec 2020 15:36:34
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).		07 Dec 2020 15:36:33
User closed query 'PV Query: Please provide the death certificate, if available. If not available, please state so.' (Site from Safety).		07 Dec 2020 15:36:31
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so.' (Site from Safety).		07 Dec 2020 15:36:28
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).		07 Dec 2020 15:36:24
Query 'PV Query: Did the patient have any prior heart attacks?' answered with 'Noted, pending medical records. Data will be updated as soon as information is available. Thank you. ' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	04 Dec 2020 15:08:30
Query 'PV Query: Did the patient had any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so.' answered with 'Noted, pending medical records. Data will be updated as soon as information is available. Thank you. ' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	04 Dec 2020 15:08:25
Query 'PV Query: Please state if any resuscitation attempt was done?' answered with 'Noted, pending medical records. Data will be updated as soon as information is available. Thank you. ' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	04 Dec 2020 15:07:46

US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
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 'Noted, pending medical records. Data will be updated as soon as information is available. Thank you. ' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	04 Dec 2020 15:07:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so.' answered with 'Noted, pending medical records. Data will be updated as soon as information is available. Thank you. ' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	04 Dec 2020 15:07:27
Query 'PV Query: Please provide the death certificate, if available. If not available, please state so.' answered with 'Noted, pending medical records. Data will be updated as soon as information is available. Thank you. ' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	04 Dec 2020 15:07:13
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'Noted, pending medical records. Data will be updated as soon as information is available. Thank you. ' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	04 Dec 2020 15:07:07
User opened query 'PV Query: Did the patient have any prior heart attacks?' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:46:35
User opened query 'PV Query: Did the patient had any presenting signs and symptoms? If yes, please provide the details. If no, then kindly state so.' (Site from Safety).		01 Dec 2020 00:46:12
User opened query 'PV Query: As per the case narrative, the subject had obesity. Please confirm if obesity is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If obesity is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).		01 Dec 2020 00:45:43
User opened query 'PV Query: Please state if any resuscitation attempt was done?' (Site from Safety).		01 Dec 2020 00:45:21

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
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)	01 Dec 2020 00:45:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none performed, please state so.' (Site from Safety).		01 Dec 2020 00:44:54
User opened query 'PV Query: Please provide the death certificate, if available. If not available, please state so.' (Site from Safety).		01 Dec 2020 00:44:43
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).		01 Dec 2020 00:44:33
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	21 Nov 2020 00:07:53
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	21 Nov 2020 00:07:53
User entered 'SAE Term: Myocardial Infarction Outcome: Fatal Causality: Not IP related Vaccination #1: 02-SEP-2020 Vaccination #2: 01-OCT-2020 C3: 30-OCT-2020 Subject's sister called our site to inform that subject passed away on 16-NOV-2020 from a massive heart attack. Subject had multiple cardiac risk factors including hypertension (2018), pre-diabetes (2019), Supraventricular tachycardia (2019), obesity, hyperlipidemia (2019), left bundle branch block (1976). Further details not available. Medical records being requested there is insufficient information to determine if there were any new concomitant medications, non-study vaccinations, prohibited medications, or COVID symptoms. Does not appear to be COVID-19 related since subject's sister reported a major heart attack. Medical records pending.' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 00:07:53

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Narrative

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 22:13:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:13:33

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	20 Nov 2020 22:13:33

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	21 Nov 2020 00:07:53

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US3322199
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:07:17
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 09 Jun 2021 17:07:17

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:33:08
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:14:46

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 00:05:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 00:05:34
Data point term sent to Coder	System	25 Sep 2020 20:15:34
User entered 'Atenolol'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

FDA-CBER-2022-1614-0776823

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Arythmia/Hypertension'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '10'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

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US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:17

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:13:46
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'updated per updated source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:14:55
User entered 'UN Jan 2019' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:14:47
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:25:54
User entered 'un Jan 2017'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

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US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Per DM CLR: Please review 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study. Kindly update eCRF otherwise provide further clarifications.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 21:18:44
Query 'Per DM CLR: Please review 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study. Kindly update eCRF otherwise provide further clarifications.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 17:04:53
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 17:04:48
User opened query 'Per DM CLR: Please review 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study. Kindly update eCRF otherwise provide further clarifications.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 19:13:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:23:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:13

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	25 Sep 2020 20:15:13

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	25 Sep 2020 20:15:13

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:07:17
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '804 (804)'	System	25 Sep 2020 20:15:13

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:16:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:16:46
Data point term sent to Coder	System	25 Sep 2020 20:16:34
User entered 'Amlodipine'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'hypertension'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776843

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '10'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776844

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776845

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776848

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776849

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'un Oct 2019'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776851

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776854

US3322199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:17

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Per DM CLR: Please review 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study. Kindly update eCRF otherwise provide further clarifications.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 17:37:22
Query 'Per DM CLR: Please review 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study. Kindly update eCRF otherwise provide further clarifications.' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 17:06:08
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 17:05:45
User opened query 'Per DM CLR: Please review 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study. Kindly update eCRF otherwise provide further clarifications.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 19:14:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:24:09
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:15:39

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776856

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776857

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:07:17
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '804 (804)'	System	25 Sep 2020 20:15:39

FDA-CBER-2022-1614-0776858

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:16:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 20:16:46
Data point term sent to Coder	System	25 Sep 2020 20:16:35
User entered 'Aspirin'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776859

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776860

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Cardiac prophylaxis'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776861

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '81'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776862

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776863

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776864

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776866

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776867

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776868

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'un Jan 2019'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776869

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776870

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776872

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:00

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776874

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776875

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:07:17
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '804 (804)'	System	25 Sep 2020 20:16:00

FDA-CBER-2022-1614-0776876

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 22:04:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 22:04:56
Data point term sent to Coder	System	25 Sep 2020 20:16:35
User entered 'Atorvastatin'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776877

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776878

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:13:58
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'will update per updated source now' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 21:15:23
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:26:49
User entered 'Hypercholestremia'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776879

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '10'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776880

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776881

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776882

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776883

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776884

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776885

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776886

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'un Jan 2019'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

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US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.	Heather Davis (b) (4) (b) (4)	08 Apr 2021 17:34:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776891

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776892

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '1'	System	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776893

US3322199
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:07:17
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User entered '804 (804)'	System	25 Sep 2020 20:16:29

FDA-CBER-2022-1614-0776894

US3322199
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 17:07:17
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Feb 2021 22:07:21

FDA-CBER-2022-1614-0776895

US3322199
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:07:17
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:20:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

FDA-CBER-2022-1614-0776896

US3322199
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:07:17
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:20:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Death (DEATH)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

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US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:17

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:20:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User closed query 'Per CDM RQ: Site response noted. Please enter in this field the AE log line number that caused the dosing discontinuation. Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 17:54:34
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	01 Dec 2020 14:35:58
User entered empty; reason for change Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 14:35:58
Query 'Per CDM RQ: Site response noted. Please enter in this field the AE log line number that caused the dosing discontinuation. Thank you!' answered with "'AE Log 1" has been entered per query resolution. Please note that an open system query has been issued because data was entered in this field but Reason for Discontinuation was "Death." Please advise if "Reason for Discontinuation" should be changed to SAE.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	30 Nov 2020 16:45:20
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	30 Nov 2020 16:41:05
User entered 'AE log 1' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	30 Nov 2020 16:41:05
User opened query 'Per CDM RQ: Site response noted. Please enter in this field the AE log line number that caused the dosing discontinuation. Thank you!' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 16:25:32
User closed query 'Per CDM-'Reason for discontinuation' is 'AE/SAE', then please enter the missing AE log line number in the 'If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify' field. ' (Site from DM).		26 Nov 2020 16:25:32

US3322199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:17

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Query 'Per CDM-‘Reason for discontinuation’ is ‘AE/SAE’, then please enter the missing AE log line number in the ‘If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify’ field. ' answered with 'Reason for discontinuation is SAE that resulted to Death. It is entered in the AE log. System query is issued when data is entered in the given field because "Death" does not include a "specify" option. Please advise and clarify how to capture this event.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	25 Nov 2020 15:32:45
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	25 Nov 2020 15:26:37
User entered empty; reason for change Per Query Resolution	Frances Saubon (b) (4) (b) (4)	25 Nov 2020 15:26:37
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	25 Nov 2020 15:25:33
User entered 'SAE Term: Myocardial Infarction Outcome: Fatal Causality: Not IP related Vaccination #1: 02-SEP-2020 Vaccination #2: 01-OCT-2020 C3: 30-OCT-202. Summary: Subject's sister called our site to inform' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	25 Nov 2020 15:25:33
User opened query 'Per CDM-‘Reason for discontinuation’ is ‘AE/SAE’, then please enter the missing AE log line number in the ‘If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify’ field. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 09:54:56
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

US3322199
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:07:17
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:20:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Adverse event (ADVERSE EVENT)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

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US3322199
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:07:17
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:20:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

FDA-CBER-2022-1614-0776901

US3322199
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:07:17
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:20:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

FDA-CBER-2022-1614-0776902

US3322199
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:07:17
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:20:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered 'Unknown (UNK)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 22:14:37

FDA-CBER-2022-1614-0776903

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'USA-US060-2020-MRNA-1273-P301000012'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776904

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776905

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776906

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776907

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776908

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776909

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776910

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776911

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Veronica'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776912

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Fragoso'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776913

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '6550 Mapleridge Street'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776914

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Houston'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776915

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'TX'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776916

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '77081'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776917

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:23:10
User entered 'US'	System	23 Nov 2020 23:35:44

FDA-CBER-2022-1614-0776918

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2'	System	08 Dec 2020 17:23:31
User entered '1'	System	23 Nov 2020 23:35:44

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'USA-US060-2020-MRNA-1273-P301000012'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776920

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776921

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776922

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776923

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776924

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776925

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776926

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776927

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Veronica'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776928

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Fragoso'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776929

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '6550 Mapleridge Street'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776930

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Houston'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776931

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'TX'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776932

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '77081'	System	23 Nov 2020 23:35:05

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:23:10
User entered 'US'	System	23 Nov 2020 23:35:44

FDA-CBER-2022-1614-0776934

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2'	System	08 Dec 2020 17:23:31
User entered '1'	System	23 Nov 2020 23:35:44

FDA-CBER-2022-1614-0776935

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 17:07:17
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '23/Nov/2020 18:35'	System	23 Nov 2020 23:35:44

FDA-CBER-2022-1614-0776936

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:07:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:23:10
User entered '1'		23 Nov 2020 23:35:44

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'USA-US060-2020-MRNA-1273-P301000012'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776938

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776939

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Yes (Y)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776940

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776941

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776942

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776943

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776944

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'No (N)'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776945

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Veronica'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776946

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Fragoso'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776947

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '6550 Mapleridge Street'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776948

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'Houston'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776949

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered 'TX'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776950

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 23:35:33
User entered '77081'	System	23 Nov 2020 23:35:05

FDA-CBER-2022-1614-0776951

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:23:10
User entered 'US'	System	23 Nov 2020 23:35:44

FDA-CBER-2022-1614-0776952

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 09 Jun 2021 17:07:17
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '2'	System	08 Dec 2020 17:23:31
User entered '1'	System	23 Nov 2020 23:35:44

FDA-CBER-2022-1614-0776953

US3322199
Folder: SAE USA-US060-2020-MRNA-1273-P301000012
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 17:07:17
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:29:22
User entered '08/Dec/2020 12:23'	System	08 Dec 2020 17:23:31

FDA-CBER-2022-1614-0776954

US3322199

Folder: SAE USA-US060-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:07:17

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:18:01
DataPoint Verified.		03 Mar 2021 18:55:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:29:22
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:28:29
User entered '1'		08 Dec 2020 17:23:31