US3732110 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:30:49

All time stamps listed in this document are displayed in GMT

US3732110
Form: Participant Creation
Data signed: (b) (4) **24 Feb 2021 23:25:20**
Generated On: 10 Jun 2021 09:30:49

Participant ID	US3732110

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-3085227

US3732110
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085228

US3732110
Folder: Screening
Form: Demographics
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Date of Birth (MMM yyyy)	(b) (6) 1939
Age	81
Age Units	YEARS
Age (Derived)	81
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-3085229

US3732110
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Date of Informed Consent *(dd MMM yyyy)*	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ■ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-3085230

US3732110
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085231

US3732110
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-3085232

US3732110
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	SOTALOL DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085233

US3732110
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	VICODIN DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085234

US3732110
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	LISINOPRIL DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085235

US3732110
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	NAPROXEN DRUG ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085236

US3732110
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	CATARACTS - RIGHT EYE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085237

US3732110
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085238

US3732110
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Start Year (derived)	1958
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085239

US3732110
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	ACTINIC KERATOSIS - SCALP
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085240

US3732110
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085241

US3732110
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085242

US3732110
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085243

US3732110
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☑ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085244

US3732110
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085245

US3732110
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Condition	GOUT RIGHT BIG TOE
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3085246

US3732110
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Were vital signs assessed?	Yes ☒ No ☐
Date of assessment *(dd MMM yyyy)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	12:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:05
Height *(xxx.x)*	183.0 cm
Weight *(xxx.x)*	96.7 kg
BMI *(xxx.x)*	28.87515 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-2022-1614-3085247

US3732110
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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

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

FDA-CBER-2022-1614-3085248

US3732110
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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	> 65 YEARS OLD, CAN'T SHELTER IN PLACE LIVES IN HIGH DENSITY HOUSING

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

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

FDA-CBER-2022-1614-3085250

US3732110
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-3085251

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

What was the date of randomization? *(dd MMM yyyy)*	20 AUG 2020
What was the participant's randomization number?	187186
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-2022-1614-3085252

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-3085253

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	12:05 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:05
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3085254

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	13:29 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 13:29
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	67 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3085255

US3732110
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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-2022-1614-3085256

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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)*	20 AUG 2020
What was the treatment time? *(00:00-23:59)*	12:59 (24 HR)
Treatment Date and Time (derived)	20 AUG 2020 12:59
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-2022-1614-3085257

US3732110
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	20 AUG 2020
Collection time *(00:00-23:59)*	12:32 (24 HR)
Collection date and time (derived)	20 AUG 2020 12:32

FDA-CBER-2022-1614-3085258

Collection date *(dd MMM yyyy)*			20 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:49	20 AUG 2020 12:49
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3085259

US3732110
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085260

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49

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**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 AUG 2020 13:32
PC Open Date & Time	20 AUG 2020 13:19
PC Close Date & Time	20 AUG 2020 15:49

FDA-CBER-2022-1614-3085261

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49

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**	95.1 °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	21 AUG 2020 08:11
PC Open Date & Time	20 AUG 2020 16:44
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-3085262

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.8 °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	22 AUG 2020 09:44
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49

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	23 AUG 2020 08:33
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-3085265

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-3085266

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.8 °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	25 AUG 2020 20:51
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49

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**	96.8 °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	27 AUG 2020 11:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3085268

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49

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	20 AUG 2020 13:34
PC Open Date & Time	20 AUG 2020 13:19
PC Close Date & Time	20 AUG 2020 15:49

FDA-CBER-2022-1614-3085269

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49

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	21 AUG 2020 08:14
PC Open Date & Time	20 AUG 2020 16:44
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-3085270

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49

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	22 AUG 2020 09:44
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-3085271

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49

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	23 AUG 2020 08:34
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
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	
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-3085273

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
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	
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-3085274

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49

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	25 AUG 2020 20:51
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-3085275

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49

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	27 AUG 2020 11:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3085276

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

FDA-CBER-2022-1614-3085277

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	20 AUG 2020 13:35
PC Open Date & Time	20 AUG 2020 13:19
PC Close Date & Time	20 AUG 2020 15:49

FDA-CBER-2022-1614-3085278

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

FDA-CBER-2022-1614-3085279

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	21 AUG 2020 08:14
PC Open Date & Time	20 AUG 2020 16:44
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-3085280

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085281

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49

	Yes ☐
PC Time stamp	22 AUG 2020 09:45
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-3085282

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085283

	Yes ☐
PC Time stamp	23 AUG 2020 08:34
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49

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-2022-1614-3085285

	Yes ☐
PC Time stamp	
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085287

	Yes ☐
PC Time stamp	
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49

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-2022-1614-3085289

	Yes ☐
PC Time stamp	25 AUG 2020 20:52
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49

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-2022-1614-3085291

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49

	Yes ☐
PC Time stamp	27 AUG 2020 11:02
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3085292

US3732110
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3085293

US3732110
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085294

US3732110
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 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-2022-1614-3085295

US3732110
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085296

US3732110
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 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-2022-1614-3085297

US3732110
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085298

US3732110
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT2

FDA-CBER-2022-1614-3085299

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	17 SEP 2020
Time of assessment *(00:00-23:59)*	10:25 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:25
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	55 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3085300

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	17 SEP 2020
Time of assessment *(00:00-23:59)*	11:33 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:33
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3085301

US3732110
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	17 SEP 2020

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

FDA-CBER-2022-1614-3085302

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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)*	17 SEP 2020
What was the treatment time? *(00:00-23:59)*	11:03 (24 HR)
Treatment Date and Time (derived)	17 SEP 2020 11:03
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

US3732110
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	17 SEP 2020
Collection time *(00:00-23:59)*	10:38 (24 HR)
Collection date and time (derived)	17 SEP 2020 10:38

FDA-CBER-2022-1614-3085304

Collection date *(dd MMM yyyy)*			17 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	17 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3085305

US3732110
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085306

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	17 SEP 2020 11:43
PC Open Date & Time	17 SEP 2020 11:23
PC Close Date & Time	17 SEP 2020 13:53

FDA-CBER-2022-1614-3085307

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49

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**	95.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 10:10
PC Open Date & Time	17 SEP 2020 14:48
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-3085308

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49

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**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 SEP 2020 10:22
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49

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**	97.4 °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	19 SEP 2020 20:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 SEP 2020 21:56
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 13:11
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-3085312

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.3 °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	22 SEP 2020 21:04
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49

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**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-3085314

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49

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	17 SEP 2020 11:44
PC Open Date & Time	17 SEP 2020 11:23
PC Close Date & Time	17 SEP 2020 13:53

FDA-CBER-2022-1614-3085315

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49

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	18 SEP 2020 10:11
PC Open Date & Time	17 SEP 2020 14:48
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-3085316

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49

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	19 SEP 2020 10:23
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49

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	19 SEP 2020 20:09
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49

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	20 SEP 2020 21:57
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-3085319

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49

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	21 SEP 2020 13:11
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-3085320

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49

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	22 SEP 2020 21:04
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-3085321

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
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	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-3085322

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085323

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	17 SEP 2020 11:44
PC Open Date & Time	17 SEP 2020 11:23
PC Close Date & Time	17 SEP 2020 13:53

FDA-CBER-2022-1614-3085324

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

FDA-CBER-2022-1614-3085325

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 10:12
PC Open Date & Time	17 SEP 2020 14:48
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-3085326

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085327

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49

	Yes ☐
PC Time stamp	19 SEP 2020 10:23
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-3085328

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085329

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49

	Yes ☐
PC Time stamp	19 SEP 2020 20:09
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-3085330

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49

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-2022-1614-3085331

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49

	Yes ☐
PC Time stamp	20 SEP 2020 21:57
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-3085332

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085333

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49

	Yes ☐
PC Time stamp	21 SEP 2020 13:12
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-3085334

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49

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-2022-1614-3085335

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49

	Yes ☐
PC Time stamp	22 SEP 2020 21:05
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-3085336

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49

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-2022-1614-3085337

	Yes ☐
PC Time stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3732110
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 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-2022-1614-3085339

US3732110
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085340

US3732110
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	01 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-2022-1614-3085341

US3732110
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085342

US3732110
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	07 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-2022-1614-3085343

US3732110
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085344

US3732110
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-3085345

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 OCT 2020
Time of assessment *(00:00-23:59)*	11:45 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:45
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3085346

US3732110
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	16 OCT 2020

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

FDA-CBER-2022-1614-3085347

US3732110
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	16 OCT 2020
Collection time *(00:00-23:59)*	12:20 (24 HR)
Collection date and time (derived)	16 OCT 2020 12:20

FDA-CBER-2022-1614-3085348

US3732110
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:22**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085349

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
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	22 OCT 2020 12:02:18
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

FDA-CBER-2022-1614-3085350

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 13:49:55
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

FDA-CBER-2022-1614-3085351

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 08:10:49
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-3085353

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	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 00:26:47
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 07:24:10
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

FDA-CBER-2022-1614-3085356

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-3085357

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 21:17:06
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

FDA-CBER-2022-1614-3085359

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 11:44:50
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

FDA-CBER-2022-1614-3085360

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 12:41:00
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

FDA-CBER-2022-1614-3085361

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 10:38:55
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

FDA-CBER-2022-1614-3085362

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 22:49:09
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

FDA-CBER-2022-1614-3085363

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 15:26:31
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 22:42:40
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

FDA-CBER-2022-1614-3085365

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please 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 ☐

FDA-CBER-2022-1614-3085366

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49

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	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

FDA-CBER-2022-1614-3085367

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

US3732110
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085369

US3732110
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085370

US3732110
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085371

US3732110
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085372

US3732110
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3085373

US3732110
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085374

US3732110
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:30:49

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-2022-1614-3085375

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-3085376

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 22:20:03**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085377

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **28 Apr 2021 22:20:03**
Generated On: 10 Jun 2021 09:30:49

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	03 FEB 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ■
Actual Dose 1	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	1
Continuing with mRNA-1273	

FDA-CBER-2022-1614-3085378

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

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **28 Apr 2021 22:20:03**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085380

US3732110
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-3085381

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **24 Feb 2021 23:25:20**
Generated On: 10 Jun 2021 09:30:49

AEID	USA-US102-2020-MRNA-1273-P30 1000003
Adverse event	DISPLACED AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD
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)*	08 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	08 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	08 OCT 2020
Hospital Discharge Date *(dd MMM yyyy)*	09 OCT 2020
Admitted to ICU?	Yes ☐ No ■

FDA-CBER-2022-1614-3085382

	Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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	

FDA-CBER-2022-1614-3085383

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **24 Feb 2021 23:25:20**
Generated On: 10 Jun 2021 09:30:49

	DURING DAY 57 SUBJECT REPORTED IMPLANTABLE DEVICE REPLACEMENT AND DURING THIS PROCEDURE IT WAS NOTED SUBJECT HAD A DISPLACED AICD LEAD WHICH RESULTED IN ONE OVERNIGHT STAY FOR OBSERVATION
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)	0

FDA-CBER-2022-1614-3085384

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **24 Feb 2021 23:25:20**
Generated On: 10 Jun 2021 09:30:49

AEID	
Adverse event	POST SURGICAL PAIN BILATERAL SHOULDERS RELATED TO DISPLACE AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD PROCEDURE
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)*	08 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	29 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

FDA-CBER-2022-1614-3085385

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **24 Feb 2021 23:25:20**
Generated On: 10 Jun 2021 09:30:49

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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1

FDA-CBER-2022-1614-3085386

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **24 Feb 2021 23:25:20**
Generated On: 10 Jun 2021 09:30:49

Admitted to ICU Derived (CSA Programming Field Only)

FDA-CBER-2022-1614-3085387

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

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

FDA-CBER-2022-1614-3085388

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ■
Indication	HYPOTHYROIDISM
Dose per administration	50
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-2022-1614-3085389

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2000
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 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	ALLOPURINOL
Prophylaxis	Yes ☐ No ■
Indication	GOUT RIGHT BIG TOE
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3085391

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1990
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 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	METROPOL SUCCINATE ER
Prophylaxis	Yes ☐
	No ■
Indication	HYPERTENSION
Dose per administration	25
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-2022-1614-3085393

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1995
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 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	ALPHA LIPOIC ACID
Prophylaxis	Yes ■ No ☐
Indication	VITAMIN DEFICIENCY
Dose per administration	300
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-2022-1614-3085395

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1990
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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	FLECAINIDE ACETATE (TAMBOCOR)
Prophylaxis	Yes ☐ No ■
Indication	ARRHYTHMIA VENTRICULAR TACHYCARDIA
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-3085397

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2000
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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	TAMULOSIN (FLOMAX)
Prophylaxis	Yes ☐ No ■
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	0.4
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 ☐

FDA-CBER-2022-1614-3085399

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2015
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 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	ASPIRIN
Prophylaxis	Yes ■ No ☐
Indication	CARDIAC HEALTH
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-2022-1614-3085401

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1980
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 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ☐ No ■
Indication	HYPERLIPIDEMIA
Dose per administration	40
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-2022-1614-3085403

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1980
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 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	KEFLEX
Prophylaxis	Yes ☐ No ■
Indication	PACEMAKER REPLACEMENT PROCEDURE
Dose per administration	250
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 ☐

FDA-CBER-2022-1614-3085405

	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)*	08 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-3085406

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085407

	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)*	08 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	COLCHICINE
Prophylaxis	Yes ☐ No ■
Indication	GOUT RIGHT BIG TOE
Dose per administration	0.6
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3085409

	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)*	01 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Name of Medication	COVID-19 VACCINE
Prophylaxis	Yes ■ No ☐
Indication	COVID-19 VACCINE
Dose per administration	0.5
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)*	24 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	24 JAN 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-3085413

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
08 OCT 2020	PACEMAKER REPLACEMENT	Medical History	
08 OCT 2020	AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD REPLACEMENT	Medical History	

FDA-CBER-2022-1614-3085414

US3732110
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:30:49

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

FDA-CBER-2022-1614-3085415

US3732110
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **31 Mar 2021 23:01:07**
Generated On: 10 Jun 2021 09:30:49

Date of study discontinuation/completion *(dd MMM yyyy)*	03 FEB 2021
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ■ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT RECEIVED OUTSIDE MODERNA VACCINE (FIRST DOSE) ON 24JAN2021. RELAYED TO SITE 03FEB2021.
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-3085416

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/OCT/2020 12:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3085418

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/NOV/2020 14:55
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

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	
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.	False

FDA-CBER-2022-1614-3085420

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Data signed: (b) (4) **24 Feb 2021 23:25:21**
Generated On: 10 Jun 2021 09:30:49

SAEID	USA-US102-2020-MRNA-1273-P301000003
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/NOV/2020 17:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3085422

US3732110
Form: Participant Creation
Generated On: 10 Jun 2021 09:30:49
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:51:25
User entered 'US3732110'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:36

US3732110
Form: Participant Creation
Generated On: 10 Jun 2021 09:30:49

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3085424

US3732110
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:59:42
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:32:01

FDA-CBER-2022-1614-3085425

US3732110
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:59:42
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:37

FDA-CBER-2022-1614-3085426

US3732110
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:59:42
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:32:01

FDA-CBER-2022-1614-3085427

US3732110
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'SCRN'	System	21 Aug 2020 17:32:01

FDA-CBER-2022-1614-3085428

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered (b) (6) 1939'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:38

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '81'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'YEARS'	System	21 Aug 2020 17:38:21

FDA-CBER-2022-1614-3085431

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '81'	System	20 Aug 2020 20:03:45

FDA-CBER-2022-1614-3085432

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered 'Male (M)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

FDA-CBER-2022-1614-3085434

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '1'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

FDA-CBER-2022-1614-3085435

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

FDA-CBER-2022-1614-3085436

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

FDA-CBER-2022-1614-3085439

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

FDA-CBER-2022-1614-3085440

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

FDA-CBER-2022-1614-3085441

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

FDA-CBER-2022-1614-3085442

US3732110
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:30:49
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:14:38
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:21

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Aug 2020'	System	20 Aug 2020 20:03:45

FDA-CBER-2022-1614-3085445

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2020'	System	20 Aug 2020 20:03:45

FDA-CBER-2022-1614-3085446

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered 'Amendment 2 (2)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered empty.	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

FDA-CBER-2022-1614-3085450

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:45

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:19:37

FDA-CBER-2022-1614-3085452

US3732110
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:30:49
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '1'	System	20 Aug 2020 20:03:50

US3732110
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:30:49
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:41
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:03:50

US3732110
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:30:49
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:16:47
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:33:09

FDA-CBER-2022-1614-3085455

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:45:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 11:45:32
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
Data point term sent to Coder	System	20 Oct 2020 15:45:22
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:45:02
User entered 'sotalol drug allergy' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:45:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:27:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 22:27:20
Data point term sent to Coder	System	21 Aug 2020 17:35:37
User entered 'allergy to sotalol'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

FDA-CBER-2022-1614-3085457

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

FDA-CBER-2022-1614-3085458

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:02

FDA-CBER-2022-1614-3085461

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2000'	System	21 Aug 2020 17:35:02

FDA-CBER-2022-1614-3085462

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2000'	System	21 Aug 2020 17:35:02

FDA-CBER-2022-1614-3085463

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	21 Aug 2020 17:35:02

FDA-CBER-2022-1614-3085464

US3732110
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	21 Aug 2020 17:35:02

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
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: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:47:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:47:47
Data point term sent to Coder	System	20 Oct 2020 15:46:23
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:45:25
User entered 'vicodin drug allergy' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:45:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:21:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:21:34
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: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:53:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 07:53:59
Data point term sent to Coder	System	16 Sep 2020 21:24:43
User entered 'allergy to hydrocodone-acetaminophen'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

FDA-CBER-2022-1614-3085468

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

FDA-CBER-2022-1614-3085471

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2000'	System	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

FDA-CBER-2022-1614-3085472

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2000'	System	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:24:21
DataPoint activated with code reason code Data required.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:23:54
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:35:42

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:47:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:47:46
Data point term sent to Coder	System	20 Oct 2020 15:46:23
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:45:41
User entered 'LISINOPRIL drug allergy' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:45:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:33
Data point term sent to Coder	System	16 Sep 2020 21:24:43
User entered 'allergy to lisinopril'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:38

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:38

FDA-CBER-2022-1614-3085477

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:38

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:38

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:38

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:38

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2000'	System	16 Sep 2020 21:24:38

FDA-CBER-2022-1614-3085482

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2000'	System	16 Sep 2020 21:24:38

FDA-CBER-2022-1614-3085483

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:24:38

US3732110
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:24:38

FDA-CBER-2022-1614-3085485

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:47:44
Data point term sent to Coder	System	20 Oct 2020 15:46:24
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:46:02
User entered 'NAPROXEN drug allergy' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:46:02
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:52
Data point term sent to Coder	System	16 Sep 2020 21:25:44
User entered 'allergy to naproxen'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

FDA-CBER-2022-1614-3085486

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

FDA-CBER-2022-1614-3085488

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

FDA-CBER-2022-1614-3085490

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:24:52

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2000'	System	16 Sep 2020 21:24:52

FDA-CBER-2022-1614-3085492

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2000'	System	16 Sep 2020 21:24:52

FDA-CBER-2022-1614-3085493

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:24:52

FDA-CBER-2022-1614-3085494

US3732110
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:24:52

FDA-CBER-2022-1614-3085495

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract (right) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:33:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:33:47
Data point term sent to Coder	System	18 Sep 2020 16:39:43
Coding entries removed.	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:38:56
User entered 'CATARACTS - right eye' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:38:56
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:53
Data point term sent to Coder	System	16 Sep 2020 21:25:44
User entered 'cataracts'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2018'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

FDA-CBER-2022-1614-3085500

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:03

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2018'	System	16 Sep 2020 21:25:03

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2018'	System	16 Sep 2020 21:25:03

FDA-CBER-2022-1614-3085503

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:25:03

US3732110
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:25:03

FDA-CBER-2022-1614-3085505

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:53
Data point term sent to Coder	System	16 Sep 2020 21:25:44
User entered 'hypothyroidism'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

FDA-CBER-2022-1614-3085506

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

FDA-CBER-2022-1614-3085507

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

FDA-CBER-2022-1614-3085510

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:17

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2000'	System	16 Sep 2020 21:25:17

FDA-CBER-2022-1614-3085512

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2000'	System	16 Sep 2020 21:25:17

FDA-CBER-2022-1614-3085513

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:25:17

US3732110
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:25:17

FDA-CBER-2022-1614-3085515

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
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)	16 Sep 2020 21:26:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:26:54
Data point term sent to Coder	System	16 Sep 2020 21:25:44
User entered 'obesity'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:27

FDA-CBER-2022-1614-3085516

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1958'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:27

FDA-CBER-2022-1614-3085517

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:27

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:27

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:27

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:25:27

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 1958'	System	16 Sep 2020 21:25:27

FDA-CBER-2022-1614-3085522

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '1958'	System	16 Sep 2020 21:25:27

FDA-CBER-2022-1614-3085523

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:25:27

FDA-CBER-2022-1614-3085524

US3732110
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:25:27

FDA-CBER-2022-1614-3085525

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:41:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:41:00
Data point term sent to Coder	System	18 Sep 2020 16:39:43
Coding entries removed.	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:39:29
User entered 'ACTINIC KERATOSIS - scalp' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:39:29
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:27:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:27:40
Data point term sent to Coder	System	16 Sep 2020 21:26:47
User entered 'actinic keratosis'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1990'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

FDA-CBER-2022-1614-3085528

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

FDA-CBER-2022-1614-3085530

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:40

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 1990'	System	16 Sep 2020 21:26:40

FDA-CBER-2022-1614-3085532

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '1990'	System	16 Sep 2020 21:26:40

FDA-CBER-2022-1614-3085533

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:26:40

US3732110
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:26:40

FDA-CBER-2022-1614-3085535

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
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)	16 Sep 2020 21:28:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:49
Data point term sent to Coder	System	16 Sep 2020 21:27:48
User entered 'hypertension'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

FDA-CBER-2022-1614-3085536

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1995'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

FDA-CBER-2022-1614-3085540

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:26:51

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 1995'	System	16 Sep 2020 21:26:51

FDA-CBER-2022-1614-3085542

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '1995'	System	16 Sep 2020 21:26:51

FDA-CBER-2022-1614-3085543

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:26:51

US3732110
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:26:51

FDA-CBER-2022-1614-3085545

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:48
Data point term sent to Coder	System	16 Sep 2020 21:27:48
User entered 'hyperlipidemia'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

FDA-CBER-2022-1614-3085546

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1980'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

FDA-CBER-2022-1614-3085548

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

FDA-CBER-2022-1614-3085550

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:06

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 1980'	System	16 Sep 2020 21:27:06

FDA-CBER-2022-1614-3085552

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '1980'	System	16 Sep 2020 21:27:06

FDA-CBER-2022-1614-3085553

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:27:06

US3732110
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:27:06

FDA-CBER-2022-1614-3085555

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:28:50
Data point term sent to Coder	System	16 Sep 2020 21:27:49
User entered 'atrial fibrillation'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

FDA-CBER-2022-1614-3085556

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

FDA-CBER-2022-1614-3085560

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:27:43

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2000'	System	16 Sep 2020 21:27:43

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2000'	System	16 Sep 2020 21:27:43

FDA-CBER-2022-1614-3085563

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:27:43

FDA-CBER-2022-1614-3085564

US3732110
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:27:43

FDA-CBER-2022-1614-3085565

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:30:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:30:54
Data point term sent to Coder	System	16 Sep 2020 21:28:49
User entered 'benign prostatic hypertrophy'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2015'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

FDA-CBER-2022-1614-3085570

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:28:01

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2015'	System	16 Sep 2020 21:28:01

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2015'	System	16 Sep 2020 21:28:01

FDA-CBER-2022-1614-3085573

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:28:01

FDA-CBER-2022-1614-3085574

US3732110
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:28:01

FDA-CBER-2022-1614-3085575

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable cardioverter defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:31:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:31:41
Data point term sent to Coder	System	16 Sep 2020 21:30:53
User entered 'automatic implantable cardioverter defibrillator'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

FDA-CBER-2022-1614-3085580

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:19

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 2000'	System	16 Sep 2020 21:30:19

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '2000'	System	16 Sep 2020 21:30:19

FDA-CBER-2022-1614-3085583

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:30:19

FDA-CBER-2022-1614-3085584

US3732110
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:30:19

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:04:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:04:20
Data point term sent to Coder	System	13 Oct 2020 20:03:58
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	13 Oct 2020 20:03:22
User entered 'GOUT Right Big toe' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	13 Oct 2020 20:03:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:31:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 21:31:43
Data point term sent to Coder	System	16 Sep 2020 21:30:53
User entered 'gout'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'un UNK 1990'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

FDA-CBER-2022-1614-3085587

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

FDA-CBER-2022-1614-3085588

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

FDA-CBER-2022-1614-3085590

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:18:28
User entered '0'	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:30:29

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'Jan 1990'	System	16 Sep 2020 21:30:29

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '1990'	System	16 Sep 2020 21:30:29

FDA-CBER-2022-1614-3085593

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:30:29

FDA-CBER-2022-1614-3085594

US3732110
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:30:49
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered empty.	System	16 Sep 2020 21:30:29

FDA-CBER-2022-1614-3085595

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:41
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:43
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:36:23
User closed query 'Per Source, "Vitals Time = 12:05". Please re-confirm with source and correct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 05:36:19
Query 'Per Source, "Vitals Time = 12:05". Please re-confirm with source and correct.' answered by data change (Site from CRA).	System	10 Nov 2020 00:56:56
User entered '12:05' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 00:56:56
User opened query 'Per Source, "Vitals Time = 12:05". Please re-confirm with source and correct.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:03:45
User entered '12:25'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

FDA-CBER-2022-1614-3085598

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered '20 Aug 2020 12:05'	System	10 Nov 2020 00:56:56
User entered '20 Aug 2020 12:25'	System	21 Aug 2020 17:37:27

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:47
User entered '183.0' cm	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27
DataPoint set to visible.	System	20 Aug 2020 20:03:50

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:49
User entered '96.7' kg	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27
DataPoint set to visible.	System	20 Aug 2020 20:03:50

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Amendment Manager: User entered '28.87515'	System	17 Sep 2020 00:16:51
User entered '28.9'	System	21 Aug 2020 17:37:27
DataPoint set to visible.	System	20 Aug 2020 20:03:50

FDA-CBER-2022-1614-3085602

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'kg/m2'	System	21 Aug 2020 17:37:27
DataPoint set to visible.	System	20 Aug 2020 20:03:50

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '98.5' F	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:54
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

FDA-CBER-2022-1614-3085606

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '71'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'bpm'	System	21 Aug 2020 17:37:27

FDA-CBER-2022-1614-3085608

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '16'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

FDA-CBER-2022-1614-3085609

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'breaths/min'	System	21 Aug 2020 17:37:27

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:55:59
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '121'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

FDA-CBER-2022-1614-3085611

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'mmHg'	System	21 Aug 2020 17:37:27

FDA-CBER-2022-1614-3085612

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 20:56:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:32:42
User entered '70'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:27

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User entered 'mmHg'	System	21 Aug 2020 17:37:27

FDA-CBER-2022-1614-3085614

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49

FDA-CBER-2022-1614-3085615

US3732110
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49

FDA-CBER-2022-1614-3085616

US3732110
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:30:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:07:20
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:39

US3732110
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:30:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:07:20
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:37:39

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:10:54
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:10:56
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:10:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:10:58
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:00
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:01
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:02
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:04
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:05
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:08
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:09
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:18:00
User closed query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:17:54
Query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' answered by data change (Site from CRA).	System	22 Oct 2020 21:57:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	22 Oct 2020 21:57:36
User opened query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:08:38
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

FDA-CBER-2022-1614-3085630

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:18:00
User closed query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:17:57
Query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' answered by data change (Site from CRA).	System	22 Oct 2020 21:57:36
User entered '> 65 years old, can't shelter in place lives in high density housing' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	22 Oct 2020 21:57:36
User opened query 'Per Source, "Other = Yes", Subject is >65 Yrs Old. Please re-review Source and correct. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:10:49
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:14
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:15
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:18
User entered '1'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:20
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:22
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:30:49
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:11:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:02

US3732110
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:04
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:43

US3732110
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:04
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:43

US3732110
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:04
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:38:43

US3732110
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'VISIT1'	System	21 Aug 2020 17:38:43

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:16
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:36

FDA-CBER-2022-1614-3085644

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:12:17
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 06:00:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:00:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 19:24:36
User entered '187186' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:36

FDA-CBER-2022-1614-3085645

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:12:19
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 19:24:36

FDA-CBER-2022-1614-3085646

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:12:21
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:58:57
Query 'PER CDM: Please complete this section of the form.' answered with 'complete ' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:15:08
User entered 'No (N)'	Lauren Arnett (b) (4)	15 Sep 2020 00:14:59
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 10:15:35

FDA-CBER-2022-1614-3085647

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:17:28
User closed query 'Per Medical HX Source; Subject has Hx of Atrial Fib, Implantable Cardio Defibrillator. Please re-confirm if this is considered part of "Significant Cardiac Disease". ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 06:17:26
Query 'Per Medical HX Source; Subject has Hx of Atrial Fib, Implantable Cardio Defibrillator. Please re-confirm if this is considered part of "Significant Cardiac Disease". ' answered with 'updated per subjects medical history' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 19:57:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 19:57:29
User opened query 'Per Medical HX Source; Subject has Hx of Atrial Fib, Implantable Cardio Defibrillator. Please re-confirm if this is considered part of "Significant Cardiac Disease". ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:14:18
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:14:59

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:14:20
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:14:59

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:14:22
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:14:59

FDA-CBER-2022-1614-3085650

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:14:24
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	15 Sep 2020 00:14:59

FDA-CBER-2022-1614-3085651

US3732110
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:30:49
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:29:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:09
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:14:25
User entered 'No (N)'	Lauren Arnett (b) (4)	22 Sep 2020 21:52:24
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:37:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:50:15

FDA-CBER-2022-1614-3085652

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:20:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:12:11
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Height

Audit	User	Time (GMT)
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:14:17
User entered '183.0' cm	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15
User entered '96.7' kg	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085655

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:20:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:12:11
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Height

Audit	User	Time (GMT)
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:14:17
User entered '183.0' cm	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15
User entered '96.7' kg	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085658

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085659

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085660

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085661

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '12:05' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 21:53:29
User entered '12:25' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085662

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '20 Aug 2020 12:05'	System	22 Sep 2020 21:53:29
User entered '20 Aug 2020 12:25'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085665

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'bpm'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085669

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'breaths/min'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '121' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085671

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Aug 2020 21:33:50
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085673

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	29 Aug 2020 21:33:50
User entered empty.	System	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:20:53
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 14:12:11
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Height

Audit	User	Time (GMT)
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to “Were vital signs assessed”, date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:14:17
User entered '183.0' cm	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:30:49
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:20:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	16 Sep 2020 21:31:15
User entered '96.7' kg	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085677

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085678

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '13:29'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '20 Aug 2020 13:29'	System	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '97.5' F	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085685

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '70'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085686

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'bpm'	System	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085687

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '18'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'breaths/min'	System	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085689

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '137'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:22
User entered '67'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:42

US3732110
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	21 Aug 2020 17:39:42

FDA-CBER-2022-1614-3085693

US3732110
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:30:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:24
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:11
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:51

FDA-CBER-2022-1614-3085694

US3732110
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:30:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:24
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:11
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:39:51

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered empty.	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085697

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
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)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered empty.	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 20:04:27

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered '12:59'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085701

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '20 Aug 2020 12:59'	System	20 Aug 2020 20:04:27

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4) (b) (4)	20 Aug 2020 20:04:27

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:24
User entered 'ONCE'	System	20 Aug 2020 20:04:27

US3732110
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 20:04:27

US3732110
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:26
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:49
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:35
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:11

US3732110
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:26
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:49
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:35
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:11

FDA-CBER-2022-1614-3085707

US3732110
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:26
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:49
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:35
User entered '12:32'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:11

US3732110
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:26
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:49
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '20 Aug 2020 12:32'	System	21 Aug 2020 17:40:11

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:30:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered '20 Aug 2020'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:30:49
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

FDA-CBER-2022-1614-3085711

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered '12:49'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:30:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '20 Aug 2020 12:49'	System	21 Aug 2020 17:40:26

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:30:49
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

FDA-CBER-2022-1614-3085715

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:56
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:26

US3732110
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:30:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 20:59:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered empty.	System	21 Aug 2020 17:40:26

US3732110
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:23:04
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:40:31

US3732110
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:25:49
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:39
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	21 Aug 2020 17:40:31

FDA-CBER-2022-1614-3085720

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085721

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:31:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '966ccd7d-c457-4b68-887b-eea81a8d31c3'	System	20 Aug 2020 20:32:24
User entered 'Yes (Y)'	System	20 Aug 2020 20:32:24

FDA-CBER-2022-1614-3085722

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '966ccd7d-c457-4b68-887b-eea81a8d31c3'	System	20 Aug 2020 20:32:24
User entered '97.5'	System	20 Aug 2020 20:32:24

FDA-CBER-2022-1614-3085723

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:11', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '966ccd7d-c457-4b68-887b-eea81a8d31c3'	System	20 Aug 2020 20:32:24
User entered 'No (N)'	System	20 Aug 2020 20:32:24

FDA-CBER-2022-1614-3085724

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '966ccd7d-c457-4b68-887b-eea81a8d31c3'	System	20 Aug 2020 20:32:24
User entered '20 Aug 2020 13:32'	System	20 Aug 2020 20:32:24

FDA-CBER-2022-1614-3085725

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 13:19'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085726

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 15:49'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085727

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085728

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:11:17', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '295be918-d8cb-4013-8ed8-310dcec094be'	System	21 Aug 2020 15:11:54
User entered 'Yes (Y)'	System	21 Aug 2020 15:11:54

FDA-CBER-2022-1614-3085729

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:11:26', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '295be918-d8cb-4013-8ed8-310dcec094be'	System	21 Aug 2020 15:11:54
User entered '95.1'	System	21 Aug 2020 15:11:54

FDA-CBER-2022-1614-3085730

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:11:33', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '295be918-d8cb-4013-8ed8-310dcec094be'	System	21 Aug 2020 15:11:54
User entered 'No (N)'	System	21 Aug 2020 15:11:54

FDA-CBER-2022-1614-3085731

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:11:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '295be918-d8cb-4013-8ed8-310dcec094be'	System	21 Aug 2020 15:11:54
User entered '21 Aug 2020 08:11'	System	21 Aug 2020 15:11:54

FDA-CBER-2022-1614-3085732

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 16:44'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085733

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085734

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 2'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085735

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e1aaa283-3f80-4f92-9089-ae154844c7fb'	System	22 Aug 2020 16:44:29
User entered 'Yes (Y)'	System	22 Aug 2020 16:44:29

FDA-CBER-2022-1614-3085736

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:14', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e1aaa283-3f80-4f92-9089-ae154844c7fb'	System	22 Aug 2020 16:44:29
User entered '96.8'	System	22 Aug 2020 16:44:29

FDA-CBER-2022-1614-3085737

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:18', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e1aaa283-3f80-4f92-9089-ae154844c7fb'	System	22 Aug 2020 16:44:29
User entered 'No (N)'	System	22 Aug 2020 16:44:29

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:26', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e1aaa283-3f80-4f92-9089-ae154844c7fb'	System	22 Aug 2020 16:44:29
User entered '22 Aug 2020 09:44'	System	22 Aug 2020 16:44:29

FDA-CBER-2022-1614-3085739

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085740

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085741

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 3'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085742

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:17', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '05e440d3-8052-4a2e-b491-28df9ebae56a'	System	23 Aug 2020 15:33:44
User entered 'Yes (Y)'	System	23 Aug 2020 15:33:44

FDA-CBER-2022-1614-3085743

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '05e440d3-8052-4a2e-b491-28df9ebae56a'	System	23 Aug 2020 15:33:44
User entered '97.6'	System	23 Aug 2020 15:33:44

FDA-CBER-2022-1614-3085744

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '05e440d3-8052-4a2e-b491-28df9ebae56a'	System	23 Aug 2020 15:33:44
User entered 'No (N)'	System	23 Aug 2020 15:33:44

FDA-CBER-2022-1614-3085745

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '05e440d3-8052-4a2e-b491-28df9ebae56a'	System	23 Aug 2020 15:33:44
User entered '23 Aug 2020 08:33'	System	23 Aug 2020 15:33:44

FDA-CBER-2022-1614-3085746

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085747

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085748

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 4'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085749

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085750

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085751

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085752

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085753

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085754

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085755

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085756

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085757

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 5'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085758

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085759

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085760

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085761

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085762

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085763

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085764

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085765

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085766

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 6'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085767

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:50:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3f754df3-2fe0-43f3-bd00-237d8eeb9848'	System	26 Aug 2020 03:51:14
User entered 'Yes (Y)'	System	26 Aug 2020 03:51:14

FDA-CBER-2022-1614-3085768

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3f754df3-2fe0-43f3-bd00-237d8eeb9848'	System	26 Aug 2020 03:51:14
User entered '96.8'	System	26 Aug 2020 03:51:14

FDA-CBER-2022-1614-3085769

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3f754df3-2fe0-43f3-bd00-237d8eeb9848'	System	26 Aug 2020 03:51:14
User entered 'No (N)'	System	26 Aug 2020 03:51:14

FDA-CBER-2022-1614-3085770

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3f754df3-2fe0-43f3-bd00-237d8eeb9848'	System	26 Aug 2020 03:51:14
User entered '25 Aug 2020 20:51'	System	26 Aug 2020 03:51:14

FDA-CBER-2022-1614-3085771

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085772

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085773

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 7'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085774

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:00:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '8ddbe6f1-32e1-41f0-9bdc-a788282becef'	System	27 Aug 2020 18:01:12
User entered 'Yes (Y)'	System	27 Aug 2020 18:01:12

FDA-CBER-2022-1614-3085775

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '8ddbe6f1-32e1-41f0-9bdc-a788282becef'	System	27 Aug 2020 18:01:12
User entered '96.8'	System	27 Aug 2020 18:01:12

FDA-CBER-2022-1614-3085776

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '8ddbe6f1-32e1-41f0-9bdc-a788282becef'	System	27 Aug 2020 18:01:12
User entered 'No (N)'	System	27 Aug 2020 18:01:12

FDA-CBER-2022-1614-3085777

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:11', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '8ddbe6f1-32e1-41f0-9bdc-a788282becef'	System	27 Aug 2020 18:01:12
User entered '27 Aug 2020 11:01'	System	27 Aug 2020 18:01:12

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085779

US3732110
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085780

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085781

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 20:34:49

FDA-CBER-2022-1614-3085782

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:32:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered 'No (N)'	System	20 Aug 2020 20:34:49

FDA-CBER-2022-1614-3085783

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:14', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered 'No (N)'	System	20 Aug 2020 20:34:49

FDA-CBER-2022-1614-3085784

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered 'None (1)'	System	20 Aug 2020 20:34:49

FDA-CBER-2022-1614-3085785

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:44', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2ccf9171-8f97-4975-9c30-64b6a0c3d97a'	System	20 Aug 2020 20:34:49
User entered '20 Aug 2020 13:34'	System	20 Aug 2020 20:34:49

FDA-CBER-2022-1614-3085786

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 13:19'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085787

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 15:49'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085788

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085789

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:12:23', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 15:14:12

FDA-CBER-2022-1614-3085790

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:12:28', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered 'No (N)'	System	21 Aug 2020 15:14:12

FDA-CBER-2022-1614-3085791

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:13:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered 'No (N)'	System	21 Aug 2020 15:14:12

FDA-CBER-2022-1614-3085792

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered 'None (1)'	System	21 Aug 2020 15:14:12

FDA-CBER-2022-1614-3085793

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3337e0ea-dd6a-4af4-a9e9-173a0f3483b7'	System	21 Aug 2020 15:14:12
User entered '21 Aug 2020 08:14'	System	21 Aug 2020 15:14:12

FDA-CBER-2022-1614-3085794

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 16:44'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085795

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085796

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 2'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085797

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:38', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered 'None (1)'	System	22 Aug 2020 16:44:57

FDA-CBER-2022-1614-3085798

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered 'No (N)'	System	22 Aug 2020 16:44:57

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered 'No (N)'	System	22 Aug 2020 16:44:57

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:51', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered 'None (1)'	System	22 Aug 2020 16:44:57

FDA-CBER-2022-1614-3085801

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:44:56', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '90c4244f-2a63-4603-8702-41ed3bf34793'	System	22 Aug 2020 16:44:57
User entered '22 Aug 2020 09:44'	System	22 Aug 2020 16:44:57

FDA-CBER-2022-1614-3085802

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085803

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085804

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 3'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085805

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered 'None (1)'	System	23 Aug 2020 15:34:13

FDA-CBER-2022-1614-3085806

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:33:57', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered 'No (N)'	System	23 Aug 2020 15:34:13

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered 'No (N)'	System	23 Aug 2020 15:34:13

FDA-CBER-2022-1614-3085808

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered 'None (1)'	System	23 Aug 2020 15:34:13

FDA-CBER-2022-1614-3085809

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4d9d809f-d9db-494b-afb7-7ec23954ab15'	System	23 Aug 2020 15:34:13
User entered '23 Aug 2020 08:34'	System	23 Aug 2020 15:34:13

FDA-CBER-2022-1614-3085810

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085811

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085812

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 4'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085813

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085815

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085816

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085817

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085818

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085819

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085820

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085821

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085822

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 5'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085823

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085824

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085825

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085826

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085827

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085828

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085829

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085830

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085831

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085832

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 6'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085833

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered 'None (1)'	System	26 Aug 2020 03:51:49

FDA-CBER-2022-1614-3085834

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered 'No (N)'	System	26 Aug 2020 03:51:49

FDA-CBER-2022-1614-3085835

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered 'No (N)'	System	26 Aug 2020 03:51:49

FDA-CBER-2022-1614-3085836

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered 'None (1)'	System	26 Aug 2020 03:51:49

FDA-CBER-2022-1614-3085837

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:48', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '601d2b53-2742-4d31-b31b-3d49f227aa9e'	System	26 Aug 2020 03:51:49
User entered '25 Aug 2020 20:51'	System	26 Aug 2020 03:51:49

FDA-CBER-2022-1614-3085838

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085839

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085840

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 7'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085841

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:20', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered 'None (1)'	System	27 Aug 2020 18:01:39

FDA-CBER-2022-1614-3085842

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered 'No (N)'	System	27 Aug 2020 18:01:39

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:27', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered 'No (N)'	System	27 Aug 2020 18:01:39

FDA-CBER-2022-1614-3085844

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:32', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered 'None (1)'	System	27 Aug 2020 18:01:39

FDA-CBER-2022-1614-3085845

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'db77d839-2e02-421e-96d0-13855e0100dc'	System	27 Aug 2020 18:01:39
User entered '27 Aug 2020 11:01'	System	27 Aug 2020 18:01:39

FDA-CBER-2022-1614-3085846

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085847

US3732110
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085848

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:04:27

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

FDA-CBER-2022-1614-3085850

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:34:56', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

FDA-CBER-2022-1614-3085851

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

FDA-CBER-2022-1614-3085852

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

FDA-CBER-2022-1614-3085853

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:06', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

FDA-CBER-2022-1614-3085854

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:10', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'None (0)'	System	20 Aug 2020 20:35:28

FDA-CBER-2022-1614-3085855

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:15', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered 'No (N)'	System	20 Aug 2020 20:35:28

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-20T13:35:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '27eee2b4-8662-4458-853f-c7ee910d27a4'	System	20 Aug 2020 20:35:28
User entered '20 Aug 2020 13:35'	System	20 Aug 2020 20:35:28

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 13:19'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085858

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 15:49'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085859

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:04:27

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:22', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

FDA-CBER-2022-1614-3085861

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

FDA-CBER-2022-1614-3085862

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

FDA-CBER-2022-1614-3085863

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:33', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

FDA-CBER-2022-1614-3085864

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

FDA-CBER-2022-1614-3085865

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'None (0)'	System	21 Aug 2020 15:14:55

FDA-CBER-2022-1614-3085866

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:48', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered 'No (N)'	System	21 Aug 2020 15:14:55

FDA-CBER-2022-1614-3085867

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-21T08:14:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '45861f7b-e0d1-48d9-a4a8-468ea861baa0'	System	21 Aug 2020 15:14:55
User entered '21 Aug 2020 08:14'	System	21 Aug 2020 15:14:55

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Aug 2020 16:44'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085869

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085870

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 2'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085871

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

FDA-CBER-2022-1614-3085872

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:14', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

FDA-CBER-2022-1614-3085874

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:23', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

FDA-CBER-2022-1614-3085875

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:27', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'None (0)'	System	22 Aug 2020 16:45:50

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered 'No (N)'	System	22 Aug 2020 16:45:50

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-22T09:45:47', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a48f542d-f3df-4f30-b03d-115554221092'	System	22 Aug 2020 16:45:50
User entered '22 Aug 2020 09:45'	System	22 Aug 2020 16:45:50

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085880

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085881

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 3'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085882

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:26', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

FDA-CBER-2022-1614-3085883

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:30', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

FDA-CBER-2022-1614-3085884

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:34', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

FDA-CBER-2022-1614-3085885

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:38', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

FDA-CBER-2022-1614-3085886

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

FDA-CBER-2022-1614-3085887

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:45', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'None (0)'	System	23 Aug 2020 15:34:55

FDA-CBER-2022-1614-3085888

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:49', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered 'No (N)'	System	23 Aug 2020 15:34:55

FDA-CBER-2022-1614-3085889

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-23T08:34:53', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'eed3342d-906b-43a0-a823-92b9363ff4e2'	System	23 Aug 2020 15:34:55
User entered '23 Aug 2020 08:34'	System	23 Aug 2020 15:34:55

FDA-CBER-2022-1614-3085890

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085891

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085892

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 4'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085893

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085894

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085895

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085896

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085897

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085898

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085899

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085900

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085901

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085902

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085903

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 5'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085904

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085905

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085906

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085907

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085908

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085909

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085910

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085911

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3085912

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085913

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085914

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 6'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085915

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:51:56', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

FDA-CBER-2022-1614-3085916

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:04', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

FDA-CBER-2022-1614-3085918

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

FDA-CBER-2022-1614-3085919

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:13', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

FDA-CBER-2022-1614-3085920

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:16', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'None (0)'	System	26 Aug 2020 03:52:33

FDA-CBER-2022-1614-3085921

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered 'No (N)'	System	26 Aug 2020 03:52:33

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-25T20:52:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '043a1911-8c90-4164-a7e6-242080594180'	System	26 Aug 2020 03:52:33
User entered '25 Aug 2020 20:52'	System	26 Aug 2020 03:52:33

FDA-CBER-2022-1614-3085923

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085924

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085925

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 7'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085926

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:43', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

FDA-CBER-2022-1614-3085927

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

FDA-CBER-2022-1614-3085928

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

FDA-CBER-2022-1614-3085929

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:54', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

FDA-CBER-2022-1614-3085930

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:01:58', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

FDA-CBER-2022-1614-3085931

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:02:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'None (0)'	System	27 Aug 2020 18:02:13

FDA-CBER-2022-1614-3085932

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:02:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered 'No (N)'	System	27 Aug 2020 18:02:13

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-08-27T11:02:10', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'f84a2122-15b6-44a1-93bd-6eb20aec32b2'	System	27 Aug 2020 18:02:13
User entered '27 Aug 2020 11:02'	System	27 Aug 2020 18:02:13

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085935

US3732110
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3085936

US3732110
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:25
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:04:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 21:37:50

FDA-CBER-2022-1614-3085937

US3732110
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:25
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:04:40
User entered '27 Aug 2020'	(b) (4), (b) (6)	29 Aug 2020 21:37:50

FDA-CBER-2022-1614-3085938

US3732110
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:25
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:04:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Aug 2020 21:37:50

US3732110
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:30:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:25
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:04:40
User entered empty.	(b) (4), (b) (6)	29 Aug 2020 21:37:50

FDA-CBER-2022-1614-3085940

US3732110
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:31:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:29
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:04:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Aug 2020 21:38:15

FDA-CBER-2022-1614-3085941

US3732110
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:31:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:29
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	29 Aug 2020 21:38:15

US3732110
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:31:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:13
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:10

FDA-CBER-2022-1614-3085943

US3732110
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:31:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:13
User entered '03 Sep 2020'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:10

FDA-CBER-2022-1614-3085944

US3732110
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:31:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:13
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:10

US3732110
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:31:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:05:13
User entered empty.	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:10

FDA-CBER-2022-1614-3085946

US3732110
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:31:29
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:40
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:05:19
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	03 Sep 2020 18:07:14

FDA-CBER-2022-1614-3085947

US3732110
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:22:41
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 05:31:29
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:51:42
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:40
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	03 Sep 2020 18:07:14

US3732110
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:11:30
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:59
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:32

FDA-CBER-2022-1614-3085949

US3732110
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:11:30
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:59
User entered '10 Sep 2020'	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:32

US3732110
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:11:30
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:59
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:32

US3732110
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:11:30
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:10:59
User entered empty.	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:32

FDA-CBER-2022-1614-3085952

US3732110
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:11:30
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:11:06
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	10 Sep 2020 22:43:35

FDA-CBER-2022-1614-3085953

US3732110
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:11:30
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:00:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	10 Sep 2020 22:43:35

FDA-CBER-2022-1614-3085954

US3732110
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:07
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:11:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:41:31

US3732110
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:07
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:11:57
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:41:31

US3732110
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:07
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:11:57
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:41:31

US3732110
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:07
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'VISIT2'	System	18 Sep 2020 16:41:31

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085959

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085960

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '10:25'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085962

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '17 Sep 2020 10:25'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '97.8' F	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085964

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered empty.	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '70'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085967

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'bpm'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '16'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085969

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'breaths/min'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '95'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085971

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:13:38
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 19:07:16
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'abnormal, NCS per investigator assessment ' (Site from System).	Amara Yilmaz (b) (4) (b) (4)	13 Oct 2020 20:06:24
User entered '55' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:05
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Sep 2020 16:42:57
User entered '58'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085973

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085975

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085976

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '11:33'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085978

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '17 Sep 2020 11:33'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '97.8' F	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085980

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered 'Oral (Oral)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered empty.	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085982

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '70'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085983

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'bpm'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '16'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085985

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'breaths/min'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '118'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:38
User entered '65'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:42:57

FDA-CBER-2022-1614-3085989

US3732110
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	18 Sep 2020 16:42:57

US3732110
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:30:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:19
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:58
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:15

US3732110
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:30:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:19
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:13:58
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:15

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered empty.	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3085994

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered empty.	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3085995

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 18:04:56

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered '11:03'	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '17 Sep 2020 11:03'	System	17 Sep 2020 18:04:56

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4) (b) (4)	17 Sep 2020 18:04:56

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:25
User entered 'ONCE'	System	17 Sep 2020 18:04:56

US3732110
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:30:49
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:31
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 18:04:56

US3732110
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:47
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:25

US3732110
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:47
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:25

US3732110
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:47
User entered '10:38'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:25

US3732110
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:36
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '17 Sep 2020 10:38'	System	18 Sep 2020 16:43:25

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:30:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User entered '17 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:30:49
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User entered '10:30'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

FDA-CBER-2022-1614-3086010

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:30:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '17 Sep 2020 10:30'	System	18 Sep 2020 16:43:38

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:30:49
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:14:56
User entered 'No (N)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:43
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:14:56
User closed query "Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:43:43
Query "Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	18 Sep 2020 16:43:43
User opened query "Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:43:38
User entered empty.	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:38

US3732110
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:30:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered empty.	System	18 Sep 2020 16:43:38

US3732110
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:47
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:15:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	18 Sep 2020 16:43:48

US3732110
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:47
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	18 Sep 2020 16:43:48

FDA-CBER-2022-1614-3086017

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086018

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:42:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00a2a04e-512d-43fd-80fe-413e21bdbee2'	System	17 Sep 2020 18:43:08
User entered 'Yes (Y)'	System	17 Sep 2020 18:43:08

FDA-CBER-2022-1614-3086019

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:42:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00a2a04e-512d-43fd-80fe-413e21bdbee2'	System	17 Sep 2020 18:43:08
User entered '97.8'	System	17 Sep 2020 18:43:08

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:42:58', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00a2a04e-512d-43fd-80fe-413e21bdbee2'	System	17 Sep 2020 18:43:08
User entered 'No (N)'	System	17 Sep 2020 18:43:08

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:43:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00a2a04e-512d-43fd-80fe-413e21bdbee2'	System	17 Sep 2020 18:43:08
User entered '17 Sep 2020 11:43'	System	17 Sep 2020 18:43:08

FDA-CBER-2022-1614-3086022

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086023

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086024

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:04:56

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:09:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2c792a24-1db9-4d9e-83ab-2addf922225c'	System	18 Sep 2020 17:10:17
User entered 'Yes (Y)'	System	18 Sep 2020 17:10:17

FDA-CBER-2022-1614-3086026

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:09:45', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2c792a24-1db9-4d9e-83ab-2addf922225c'	System	18 Sep 2020 17:10:17
User entered '95.5'	System	18 Sep 2020 17:10:17

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:10:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2c792a24-1db9-4d9e-83ab-2addf922225c'	System	18 Sep 2020 17:10:17
User entered 'No (N)'	System	18 Sep 2020 17:10:17

FDA-CBER-2022-1614-3086028

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:10:13', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2c792a24-1db9-4d9e-83ab-2addf922225c'	System	18 Sep 2020 17:10:17
User entered '18 Sep 2020 10:10'	System	18 Sep 2020 17:10:17

FDA-CBER-2022-1614-3086029

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086030

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086031

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 2'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086032

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e8bc7d3b-0c81-4d56-953f-0ee38d7d192d'	System	19 Sep 2020 17:22:28
User entered 'Yes (Y)'	System	19 Sep 2020 17:22:28

FDA-CBER-2022-1614-3086033

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:13', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e8bc7d3b-0c81-4d56-953f-0ee38d7d192d'	System	19 Sep 2020 17:22:28
User entered '97.6'	System	19 Sep 2020 17:22:28

FDA-CBER-2022-1614-3086034

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:19', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e8bc7d3b-0c81-4d56-953f-0ee38d7d192d'	System	19 Sep 2020 17:22:28
User entered 'No (N)'	System	19 Sep 2020 17:22:28

FDA-CBER-2022-1614-3086035

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e8bc7d3b-0c81-4d56-953f-0ee38d7d192d'	System	19 Sep 2020 17:22:28
User entered '19 Sep 2020 10:22'	System	19 Sep 2020 17:22:28

FDA-CBER-2022-1614-3086036

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086037

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086038

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 3'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086039

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '18e6ca0c-bcd6-40c0-8555-9ea2128122ca'	System	20 Sep 2020 03:08:44
User entered 'Yes (Y)'	System	20 Sep 2020 03:08:44

FDA-CBER-2022-1614-3086040

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:30', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '18e6ca0c-bcd6-40c0-8555-9ea2128122ca'	System	20 Sep 2020 03:08:44
User entered '97.4'	System	20 Sep 2020 03:08:44

FDA-CBER-2022-1614-3086041

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '18e6ca0c-bcd6-40c0-8555-9ea2128122ca'	System	20 Sep 2020 03:08:44
User entered 'No (N)'	System	20 Sep 2020 03:08:44

FDA-CBER-2022-1614-3086042

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '18e6ca0c-bcd6-40c0-8555-9ea2128122ca'	System	20 Sep 2020 03:08:44
User entered '19 Sep 2020 20:08'	System	20 Sep 2020 03:08:44

FDA-CBER-2022-1614-3086043

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086044

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086045

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 4'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086046

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '49b5bef1-370f-4da9-ad10-51fd89cdfc25'	System	21 Sep 2020 04:56:51
User entered 'Yes (Y)'	System	21 Sep 2020 04:56:51

FDA-CBER-2022-1614-3086047

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:32', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '49b5bef1-370f-4da9-ad10-51fd89cdfc25'	System	21 Sep 2020 04:56:51
User entered '96.9'	System	21 Sep 2020 04:56:51

FDA-CBER-2022-1614-3086048

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '49b5bef1-370f-4da9-ad10-51fd89cdfc25'	System	21 Sep 2020 04:56:51
User entered 'No (N)'	System	21 Sep 2020 04:56:51

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:49', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '49b5bef1-370f-4da9-ad10-51fd89cdfc25'	System	21 Sep 2020 04:56:51
User entered '20 Sep 2020 21:56'	System	21 Sep 2020 04:56:51

FDA-CBER-2022-1614-3086050

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086051

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086052

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 5'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086053

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2329f0e3-f3f0-4a62-b7c1-54836252e435'	System	21 Sep 2020 20:11:29
User entered 'Yes (Y)'	System	21 Sep 2020 20:11:29

FDA-CBER-2022-1614-3086054

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:16', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2329f0e3-f3f0-4a62-b7c1-54836252e435'	System	21 Sep 2020 20:11:29
User entered '96.0'	System	21 Sep 2020 20:11:29

FDA-CBER-2022-1614-3086055

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:22', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2329f0e3-f3f0-4a62-b7c1-54836252e435'	System	21 Sep 2020 20:11:29
User entered 'No (N)'	System	21 Sep 2020 20:11:29

FDA-CBER-2022-1614-3086056

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:26', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '2329f0e3-f3f0-4a62-b7c1-54836252e435'	System	21 Sep 2020 20:11:29
User entered '21 Sep 2020 13:11'	System	21 Sep 2020 20:11:29

FDA-CBER-2022-1614-3086057

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086058

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086059

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 6'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086060

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:04', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd1919c64-7be8-4107-b666-2be76a3ed9dd'	System	23 Sep 2020 04:04:26
User entered 'Yes (Y)'	System	23 Sep 2020 04:04:26

FDA-CBER-2022-1614-3086061

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:10', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd1919c64-7be8-4107-b666-2be76a3ed9dd'	System	23 Sep 2020 04:04:26
User entered '96.3'	System	23 Sep 2020 04:04:26

FDA-CBER-2022-1614-3086062

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:15', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd1919c64-7be8-4107-b666-2be76a3ed9dd'	System	23 Sep 2020 04:04:26
User entered 'No (N)'	System	23 Sep 2020 04:04:26

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:22', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd1919c64-7be8-4107-b666-2be76a3ed9dd'	System	23 Sep 2020 04:04:26
User entered '22 Sep 2020 21:04'	System	23 Sep 2020 04:04:26

FDA-CBER-2022-1614-3086064

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086065

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086066

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 7'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086067

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086068

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086069

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086071

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086072

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086073

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086074

US3732110
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086075

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086076

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:43:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered 'None (1)'	System	17 Sep 2020 18:44:07

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:43:37', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered 'No (N)'	System	17 Sep 2020 18:44:07

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:43:47', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered 'No (N)'	System	17 Sep 2020 18:44:07

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered 'None (1)'	System	17 Sep 2020 18:44:07

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38f46d18-6170-43f0-885b-c415a50ecf1f'	System	17 Sep 2020 18:44:07
User entered '17 Sep 2020 11:44'	System	17 Sep 2020 18:44:07

FDA-CBER-2022-1614-3086081

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086082

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086083

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:04:56

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:10:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered 'None (1)'	System	18 Sep 2020 17:11:26

FDA-CBER-2022-1614-3086085

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:02', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered 'No (N)'	System	18 Sep 2020 17:11:26

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered 'No (N)'	System	18 Sep 2020 17:11:26

FDA-CBER-2022-1614-3086087

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:17', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered 'None (1)'	System	18 Sep 2020 17:11:26

FDA-CBER-2022-1614-3086088

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'e39e84f2-74ac-4fc6-a435-109e325fa9ce'	System	18 Sep 2020 17:11:26
User entered '18 Sep 2020 10:11'	System	18 Sep 2020 17:11:26

FDA-CBER-2022-1614-3086089

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086090

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086091

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 2'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086092

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered 'None (1)'	System	19 Sep 2020 17:23:08

FDA-CBER-2022-1614-3086093

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered 'No (N)'	System	19 Sep 2020 17:23:08

FDA-CBER-2022-1614-3086094

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:22:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered 'No (N)'	System	19 Sep 2020 17:23:08

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered 'None (1)'	System	19 Sep 2020 17:23:08

FDA-CBER-2022-1614-3086096

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:06', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '00477942-1adc-4e1e-85c3-39c1801d1cc2'	System	19 Sep 2020 17:23:08
User entered '19 Sep 2020 10:23'	System	19 Sep 2020 17:23:08

FDA-CBER-2022-1614-3086097

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086098

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086099

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 3'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086100

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:08:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered 'None (1)'	System	20 Sep 2020 03:09:25

FDA-CBER-2022-1614-3086101

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:03', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered 'No (N)'	System	20 Sep 2020 03:09:25

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered 'No (N)'	System	20 Sep 2020 03:09:25

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:20', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered 'None (1)'	System	20 Sep 2020 03:09:25

FDA-CBER-2022-1614-3086104

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:24', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5e806739-0e29-4bf8-8df7-0a8d71c1c0d2'	System	20 Sep 2020 03:09:25
User entered '19 Sep 2020 20:09'	System	20 Sep 2020 03:09:25

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086106

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086107

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 4'	System	17 Sep 2020 18:04:56

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:56:57', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered 'None (1)'	System	21 Sep 2020 04:57:18

FDA-CBER-2022-1614-3086109

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered 'No (N)'	System	21 Sep 2020 04:57:18

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered 'No (N)'	System	21 Sep 2020 04:57:18

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:11', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered 'None (1)'	System	21 Sep 2020 04:57:18

FDA-CBER-2022-1614-3086112

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:15', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '408d13f8-70b2-48d9-b354-8b76347f5135'	System	21 Sep 2020 04:57:18
User entered '20 Sep 2020 21:57'	System	21 Sep 2020 04:57:18

FDA-CBER-2022-1614-3086113

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086114

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086115

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 5'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086116

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:33', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered 'None (1)'	System	21 Sep 2020 20:11:49

FDA-CBER-2022-1614-3086117

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:37', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered 'No (N)'	System	21 Sep 2020 20:11:49

FDA-CBER-2022-1614-3086118

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered 'No (N)'	System	21 Sep 2020 20:11:49

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:45', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered 'None (1)'	System	21 Sep 2020 20:11:49

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:48', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '4f38f475-a3aa-427e-898e-720c8f944c55'	System	21 Sep 2020 20:11:49
User entered '21 Sep 2020 13:11'	System	21 Sep 2020 20:11:49

FDA-CBER-2022-1614-3086121

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086122

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086123

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 6'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086124

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered 'None (1)'	System	23 Sep 2020 04:04:54

FDA-CBER-2022-1614-3086125

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered 'No (N)'	System	23 Sep 2020 04:04:54

FDA-CBER-2022-1614-3086126

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered 'No (N)'	System	23 Sep 2020 04:04:54

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:44', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered 'None (1)'	System	23 Sep 2020 04:04:54

FDA-CBER-2022-1614-3086128

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:52', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9b91bc85-d818-435c-8665-63e81b44637d'	System	23 Sep 2020 04:04:54
User entered '22 Sep 2020 21:04'	System	23 Sep 2020 04:04:54

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086130

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086131

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 7'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086132

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086133

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086135

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086136

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086137

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086138

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086139

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086140

US3732110
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086141

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086142

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

FDA-CBER-2022-1614-3086143

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:18', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

FDA-CBER-2022-1614-3086144

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

FDA-CBER-2022-1614-3086145

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

FDA-CBER-2022-1614-3086146

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:28', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

FDA-CBER-2022-1614-3086147

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:32', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'None (0)'	System	17 Sep 2020 18:44:42

FDA-CBER-2022-1614-3086148

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered 'No (N)'	System	17 Sep 2020 18:44:42

FDA-CBER-2022-1614-3086149

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-17T11:44:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1c239ce1-d69d-406e-ba7b-404485b17e0f'	System	17 Sep 2020 18:44:42
User entered '17 Sep 2020 11:44'	System	17 Sep 2020 18:44:42

FDA-CBER-2022-1614-3086150

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086151

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086152

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 18:04:56

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

FDA-CBER-2022-1614-3086154

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

FDA-CBER-2022-1614-3086155

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

FDA-CBER-2022-1614-3086156

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:43', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

FDA-CBER-2022-1614-3086157

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:47', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

FDA-CBER-2022-1614-3086158

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'None (0)'	System	18 Sep 2020 17:12:05

FDA-CBER-2022-1614-3086159

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:11:55', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered 'No (N)'	System	18 Sep 2020 17:12:05

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-18T10:12:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '150f6549-18cd-4e0c-be33-1a892d1f9f53'	System	18 Sep 2020 17:12:05
User entered '18 Sep 2020 10:12'	System	18 Sep 2020 17:12:05

FDA-CBER-2022-1614-3086161

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086162

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086163

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 2'	System	17 Sep 2020 18:04:56

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:14', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

FDA-CBER-2022-1614-3086165

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:18', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:22', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

FDA-CBER-2022-1614-3086168

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

FDA-CBER-2022-1614-3086169

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:38', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'None (0)'	System	19 Sep 2020 17:23:51

FDA-CBER-2022-1614-3086170

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:45', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered 'No (N)'	System	19 Sep 2020 17:23:51

FDA-CBER-2022-1614-3086171

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T10:23:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'a2be35c6-4407-486f-a67e-3a5ff8940859'	System	19 Sep 2020 17:23:51
User entered '19 Sep 2020 10:23'	System	19 Sep 2020 17:23:51

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086173

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086174

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 3'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086175

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:29', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

FDA-CBER-2022-1614-3086176

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:33', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

FDA-CBER-2022-1614-3086177

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:36', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

FDA-CBER-2022-1614-3086178

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

FDA-CBER-2022-1614-3086179

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:43', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

FDA-CBER-2022-1614-3086180

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'None (0)'	System	20 Sep 2020 03:09:59

FDA-CBER-2022-1614-3086181

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:51', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered 'No (N)'	System	20 Sep 2020 03:09:59

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-19T20:09:57', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '9a7b12a1-ad06-4979-bf20-59f7523080d1'	System	20 Sep 2020 03:09:59
User entered '19 Sep 2020 20:09'	System	20 Sep 2020 03:09:59

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086184

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086185

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 4'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086186

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:21', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

FDA-CBER-2022-1614-3086187

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

FDA-CBER-2022-1614-3086188

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:28', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

FDA-CBER-2022-1614-3086189

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:32', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

FDA-CBER-2022-1614-3086190

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

FDA-CBER-2022-1614-3086191

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:38', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'None (0)'	System	21 Sep 2020 04:57:49

FDA-CBER-2022-1614-3086192

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:42', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered 'No (N)'	System	21 Sep 2020 04:57:49

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-20T21:57:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '1bf35975-742e-4567-8895-3eb87eac37aa'	System	21 Sep 2020 04:57:49
User entered '20 Sep 2020 21:57'	System	21 Sep 2020 04:57:49

FDA-CBER-2022-1614-3086194

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086195

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086196

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 5'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086197

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:54', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:11:57', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:01', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:04', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:07', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'None (0)'	System	21 Sep 2020 20:12:18

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered 'No (N)'	System	21 Sep 2020 20:12:18

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-21T13:12:16', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '96fb0d94-4edb-4b22-93fc-0908bfcd7f99'	System	21 Sep 2020 20:12:18
User entered '21 Sep 2020 13:12'	System	21 Sep 2020 20:12:18

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086206

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086207

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 6'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086208

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:04:58', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:02', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

FDA-CBER-2022-1614-3086210

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:08', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

FDA-CBER-2022-1614-3086211

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:12', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:16', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:19', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'None (0)'	System	23 Sep 2020 04:05:30

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:23', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered 'No (N)'	System	23 Sep 2020 04:05:30

FDA-CBER-2022-1614-3086215

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-09-22T21:05:27', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3b875891-f033-4e8b-9cd8-ee166b9a5d3b'	System	23 Sep 2020 04:05:30
User entered '22 Sep 2020 21:05'	System	23 Sep 2020 04:05:30

FDA-CBER-2022-1614-3086216

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086217

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086218

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	17 Sep 2020 18:04:56
User entered 'Day 7'	System	17 Sep 2020 18:04:56

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086220

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086221

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086222

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086223

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086224

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086225

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
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)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086226

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59

FDA-CBER-2022-1614-3086227

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086228

US3732110
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:30:49
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 18:04:56

FDA-CBER-2022-1614-3086229

US3732110
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:55
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:15:44
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	24 Sep 2020 20:17:56

FDA-CBER-2022-1614-3086230

US3732110
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:55
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:15:44
User entered '24 Sep 2020'	Sylvia Lindholm (b) (4)	24 Sep 2020 20:17:56

FDA-CBER-2022-1614-3086231

US3732110
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:55
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:15:44
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	24 Sep 2020 20:17:56

US3732110
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:01:55
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:15:44
User entered empty.	Sylvia Lindholm (b) (4)	24 Sep 2020 20:17:56

FDA-CBER-2022-1614-3086233

US3732110
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:05
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:16:39
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	24 Sep 2020 20:18:02

US3732110
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:05
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	24 Sep 2020 20:18:02

US3732110
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:40
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	01 Oct 2020 18:02:40

US3732110
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:40
User entered '01 Oct 2020'	Linda Vega (b) (4) (b) (4)	01 Oct 2020 18:02:40

US3732110
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:40
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	01 Oct 2020 18:02:40

US3732110
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:40
User entered empty.	Linda Vega (b) (4) (b) (4)	01 Oct 2020 18:02:40

US3732110
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:18:48
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	01 Oct 2020 18:02:45

FDA-CBER-2022-1614-3086240

US3732110
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:17
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	01 Oct 2020 18:02:45

FDA-CBER-2022-1614-3086241

US3732110
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:23:39
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	07 Oct 2020 21:29:48

FDA-CBER-2022-1614-3086242

US3732110
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:23:39
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 09:17:39
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as is, visit occurred 21 days after visit 2' (Site from System).	Lauren Arnett (b) (4) (b) (4)	08 Oct 2020 16:40:06
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 21:29:48
User entered '07 Oct 2020'	Linda Vega (b) (4) (b) (4)	07 Oct 2020 21:29:48

US3732110
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:23:39
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	07 Oct 2020 21:29:48

FDA-CBER-2022-1614-3086244

US3732110
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:23:39
User entered empty.	Linda Vega (b) (4) (b) (4)	07 Oct 2020 21:29:48

FDA-CBER-2022-1614-3086245

US3732110
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 22:38:28
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	07 Oct 2020 21:29:52

FDA-CBER-2022-1614-3086246

US3732110
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	07 Oct 2020 21:29:52

FDA-CBER-2022-1614-3086247

US3732110
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:08

FDA-CBER-2022-1614-3086248

US3732110
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:08

FDA-CBER-2022-1614-3086249

US3732110
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:08

FDA-CBER-2022-1614-3086250

US3732110
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'VISIT3'	System	20 Oct 2020 15:48:08

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

FDA-CBER-2022-1614-3086252

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

FDA-CBER-2022-1614-3086253

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '11:45'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

FDA-CBER-2022-1614-3086254

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '16 Oct 2020 11:45'	System	20 Oct 2020 15:49:10

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '98.7' F	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

FDA-CBER-2022-1614-3086256

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

FDA-CBER-2022-1614-3086257

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '63'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'bpm'	System	20 Oct 2020 15:49:10

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '15'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

FDA-CBER-2022-1614-3086261

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'breaths/min'	System	20 Oct 2020 15:49:10

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '116'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

FDA-CBER-2022-1614-3086263

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	20 Oct 2020 15:49:10

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '67'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:10

FDA-CBER-2022-1614-3086265

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered 'mmHg'	System	20 Oct 2020 15:49:10

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51

FDA-CBER-2022-1614-3086267

US3732110
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:30:49
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51

FDA-CBER-2022-1614-3086268

US3732110
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:30:49
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:26

FDA-CBER-2022-1614-3086269

US3732110
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:30:49
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:48:26

FDA-CBER-2022-1614-3086270

US3732110
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:27

FDA-CBER-2022-1614-3086271

US3732110
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:27

FDA-CBER-2022-1614-3086272

US3732110
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '12:20'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:27

US3732110
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:02:58
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '16 Oct 2020 12:20'	System	20 Oct 2020 15:49:27

FDA-CBER-2022-1614-3086274

US3732110
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:03:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:49:31

FDA-CBER-2022-1614-3086275

US3732110
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:03:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	20 Oct 2020 15:49:31

FDA-CBER-2022-1614-3086276

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 64'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3086277

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:01:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'Yes (Y)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:01:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'No (N)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:01:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'No (N)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:01:48', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'Yes (Y)'	System	22 Oct 2020 19:02:31

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:02:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Oct 2020 19:02:31

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-22T12:02:18', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '87530735-dc58-4a8b-9fe5-1f7f5b4ea9c4'	System	22 Oct 2020 19:02:31
User entered '22 Oct 2020 12:02:18'	System	22 Oct 2020 19:02:31

FDA-CBER-2022-1614-3086283

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 20:04:27

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3086285

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 71'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3086286

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-29T13:49:44', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'ca9c0ae4-bb01-43e0-936b-73831d4d6575'	System	29 Oct 2020 20:50:09
User entered 'No (N)'	System	29 Oct 2020 20:50:09

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-29T13:49:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'ca9c0ae4-bb01-43e0-936b-73831d4d6575'	System	29 Oct 2020 20:50:09
User entered 'No (N)'	System	29 Oct 2020 20:50:09

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-10-29T13:49:55', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'ca9c0ae4-bb01-43e0-936b-73831d4d6575'	System	29 Oct 2020 20:50:09
User entered '29 Oct 2020 13:49:55'	System	29 Oct 2020 20:50:09

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3086290

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3086291

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 78'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3086292

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-03T08:10:34', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38295953-36ad-4be9-bfe1-b075f57950a0'	System	03 Nov 2020 16:10:52
User entered 'No (N)'	System	03 Nov 2020 16:10:52

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

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)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-03T08:10:43', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38295953-36ad-4be9-bfe1-b075f57950a0'	System	03 Nov 2020 16:10:52
User entered 'No (N)'	System	03 Nov 2020 16:10:52

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-03T08:10:49', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '38295953-36ad-4be9-bfe1-b075f57950a0'	System	03 Nov 2020 16:10:52
User entered '03 Nov 2020 08:10:49'	System	03 Nov 2020 16:10:52

FDA-CBER-2022-1614-3086295

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3086296

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:18:59
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 20:04:27

FDA-CBER-2022-1614-3086297

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36
Data entry locked.	System	20 Aug 2020 20:04:27
User entered 'Day 92'	System	20 Aug 2020 20:04:27

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086301

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086308

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086309

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086311

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086320

US3732110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086322

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086323

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 20:04:27

US3732110
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:19:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:06:36
Data entry locked.	System	20 Aug 2020 20:04:27
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 20:04:27

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-25T00:26:35', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5607e372-f70c-42b2-8037-f44d7ccb7712'	System	25 Nov 2020 08:26:51
User entered 'No (N)'	System	25 Nov 2020 08:26:51

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-25T00:26:41', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5607e372-f70c-42b2-8037-f44d7ccb7712'	System	25 Nov 2020 08:26:51
User entered 'No (N)'	System	25 Nov 2020 08:26:51

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-11-25T00:26:47', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '5607e372-f70c-42b2-8037-f44d7ccb7712'	System	25 Nov 2020 08:26:51
User entered '25 Nov 2020 00:26:47'	System	25 Nov 2020 08:26:51

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086331

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-01T07:24:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '477a0602-6d00-423f-b503-a9cf0d893636'	System	01 Dec 2020 15:24:15
User entered 'No (N)'	System	01 Dec 2020 15:24:15

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-01T07:24:05', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '477a0602-6d00-423f-b503-a9cf0d893636'	System	01 Dec 2020 15:24:15
User entered 'No (N)'	System	01 Dec 2020 15:24:15

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-01T07:24:10', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '477a0602-6d00-423f-b503-a9cf0d893636'	System	01 Dec 2020 15:24:15
User entered '01 Dec 2020 07:24:10'	System	01 Dec 2020 15:24:15

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086344

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086345

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086346

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086347

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086348

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086349

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086351

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086353

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086354

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086355

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086356

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086357

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086358

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086359

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086363

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-12T21:16:54', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd29a6a98-80d7-4e16-b9c1-fb4c9bea424d'	System	13 Dec 2020 05:17:07
User entered 'No (N)'	System	13 Dec 2020 05:17:07

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-12T21:17:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd29a6a98-80d7-4e16-b9c1-fb4c9bea424d'	System	13 Dec 2020 05:17:07
User entered 'No (N)'	System	13 Dec 2020 05:17:07

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-12T21:17:06', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: 'd29a6a98-80d7-4e16-b9c1-fb4c9bea424d'	System	13 Dec 2020 05:17:07
User entered '12 Dec 2020 21:17:06'	System	13 Dec 2020 05:17:07

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086371

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-19T11:44:39', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3a54c1f6-a65d-4f3c-af35-0dac2260d810'	System	19 Dec 2020 19:44:53
User entered 'No (N)'	System	19 Dec 2020 19:44:53

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-19T11:44:44', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3a54c1f6-a65d-4f3c-af35-0dac2260d810'	System	19 Dec 2020 19:44:53
User entered 'No (N)'	System	19 Dec 2020 19:44:53

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-19T11:44:50', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '3a54c1f6-a65d-4f3c-af35-0dac2260d810'	System	19 Dec 2020 19:44:53
User entered '19 Dec 2020 11:44:50'	System	19 Dec 2020 19:44:53

FDA-CBER-2022-1614-3086375

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-28T12:40:04', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '625029f3-9a84-4fb9-8121-93e0e702c770'	System	28 Dec 2020 20:41:07
User entered 'No (N)'	System	28 Dec 2020 20:41:07

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-28T12:40:56', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '625029f3-9a84-4fb9-8121-93e0e702c770'	System	28 Dec 2020 20:41:07
User entered 'No (N)'	System	28 Dec 2020 20:41:07

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2020-12-28T12:41:00', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '625029f3-9a84-4fb9-8121-93e0e702c770'	System	28 Dec 2020 20:41:07
User entered '28 Dec 2020 12:41:00'	System	28 Dec 2020 20:41:07

FDA-CBER-2022-1614-3086381

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-02T10:38:46', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '948f16ca-00b6-40eb-a83f-e9f9e093f4b7'	System	02 Jan 2021 18:38:57
User entered 'No (N)'	System	02 Jan 2021 18:38:57

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-02T10:38:51', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '948f16ca-00b6-40eb-a83f-e9f9e093f4b7'	System	02 Jan 2021 18:38:57
User entered 'No (N)'	System	02 Jan 2021 18:38:57

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-02T10:38:55', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '948f16ca-00b6-40eb-a83f-e9f9e093f4b7'	System	02 Jan 2021 18:38:57
User entered '02 Jan 2021 10:38:55'	System	02 Jan 2021 18:38:57

FDA-CBER-2022-1614-3086387

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-11T22:48:54', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '544a3f36-a2b2-45bb-8bf9-4cd5757a57fa'	System	12 Jan 2021 06:49:12
User entered 'No (N)'	System	12 Jan 2021 06:49:12

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-11T22:49:02', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '544a3f36-a2b2-45bb-8bf9-4cd5757a57fa'	System	12 Jan 2021 06:49:12
User entered 'No (N)'	System	12 Jan 2021 06:49:12

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-11T22:49:09', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '544a3f36-a2b2-45bb-8bf9-4cd5757a57fa'	System	12 Jan 2021 06:49:12
User entered '11 Jan 2021 22:49:09'	System	12 Jan 2021 06:49:12

FDA-CBER-2022-1614-3086393

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-18T15:26:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '013254c7-119d-4fbb-a3ac-bb6c5fd56387'	System	18 Jan 2021 23:26:34
User entered 'No (N)'	System	18 Jan 2021 23:26:34

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-18T15:26:27', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '013254c7-119d-4fbb-a3ac-bb6c5fd56387'	System	18 Jan 2021 23:26:34
User entered 'No (N)'	System	18 Jan 2021 23:26:34

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-18T15:26:31', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '013254c7-119d-4fbb-a3ac-bb6c5fd56387'	System	18 Jan 2021 23:26:34
User entered '18 Jan 2021 15:26:31'	System	18 Jan 2021 23:26:34

FDA-CBER-2022-1614-3086399

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-23T22:42:25', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '30e56e00-edb4-4877-b00f-f5335e599d83'	System	24 Jan 2021 06:42:44
User entered 'No (N)'	System	24 Jan 2021 06:42:44

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-23T22:42:34', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '30e56e00-edb4-4877-b00f-f5335e599d83'	System	24 Jan 2021 06:42:44
User entered 'No (N)'	System	24 Jan 2021 06:42:44

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DDFE6000-3D94-412D-BEA3-1EE37C4503BD)', Time: '2021-01-23T22:42:40', User OID: 'PatientReportedOutcome (US3732110)', ODM File OID: '30e56e00-edb4-4877-b00f-f5335e599d83'	System	24 Jan 2021 06:42:44
User entered '23 Jan 2021 22:42:40'	System	24 Jan 2021 06:42:44

FDA-CBER-2022-1614-3086405

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086406

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:06:36

FDA-CBER-2022-1614-3086407

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:06:36

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:06:36

US3732110
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:30:49
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Activated.	System	24 Mar 2021 16:39:03
DataPoint Inactivated.	System	04 Feb 2021 02:20:31
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:06:36
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:06:36

US3732110
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:03:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:05

FDA-CBER-2022-1614-3086436

US3732110
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:03:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '12 Nov 2020'	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:05

FDA-CBER-2022-1614-3086437

US3732110
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:03:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:05

US3732110
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:03:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:05

FDA-CBER-2022-1614-3086439

US3732110
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:03:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	12 Nov 2020 19:18:10

FDA-CBER-2022-1614-3086440

US3732110
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:06:44
Data hard unlocked.	(b) (4), (b) (6)	01 Apr 2021 21:03:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:37:51
User entered '1'	System	12 Nov 2020 19:18:10

FDA-CBER-2022-1614-3086441

US3732110
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	16 Dec 2020 17:18:58

US3732110
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '16 Dec 2020'	Linda Vega (b) (4) (b) (4)	16 Dec 2020 17:18:58

FDA-CBER-2022-1614-3086443

US3732110
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	16 Dec 2020 17:18:58

FDA-CBER-2022-1614-3086444

US3732110
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Linda Vega (b) (4) (b) (4)	16 Dec 2020 17:18:58

FDA-CBER-2022-1614-3086445

US3732110
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	16 Dec 2020 17:19:04

FDA-CBER-2022-1614-3086446

US3732110
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:51:55
User entered '1'	System	16 Dec 2020 17:19:04

FDA-CBER-2022-1614-3086447

US3732110
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	15 Jan 2021 19:04:10

FDA-CBER-2022-1614-3086448

US3732110
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '15 Jan 2021'	Linda Vega (b) (4) (b) (4)	15 Jan 2021 19:04:10

FDA-CBER-2022-1614-3086449

US3732110
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	15 Jan 2021 19:04:10

FDA-CBER-2022-1614-3086450

US3732110
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:30:49
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Linda Vega (b) (4) (b) (4)	15 Jan 2021 19:04:10

FDA-CBER-2022-1614-3086451

US3732110
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Feb 2021 20:12:12
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	15 Jan 2021 19:04:15

FDA-CBER-2022-1614-3086452

US3732110
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:30:49
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:33:12
User entered empty.	System	08 Feb 2021 20:12:12
User entered '1'	System	15 Jan 2021 19:04:15

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered 'No (N)'	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:47

FDA-CBER-2022-1614-3086454

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:47

FDA-CBER-2022-1614-3086455

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:47

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:30:49
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered 'UNBLND_DECIDE'	System	20 Apr 2021 21:27:47

FDA-CBER-2022-1614-3086457

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User closed query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 21:10:55
Query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. ' answered with 'subject did not sign updated informed consent, decision visit was not completed' (Site from DM).	Linda Vega (b) (4) (b) (4)	22 Apr 2021 17:01:10
User opened query 'Per CDM: Informed Consent Date is missing. Kindly review and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 13:14:05
User closed query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box." ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:36:05
Query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box." ' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4) (b) (4)	07 Apr 2021 18:18:15
User opened query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box." ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:43:34
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
Signature has been broken.	He (Helen) Pu (b) (4) (b) (4)	16 Apr 2021 21:58:38
User entered '0' reason for change: Data Entry Error	He (Helen) Pu (b) (4) (b) (4)	16 Apr 2021 21:58:38
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 20:58:35
Signature has been broken.	Gordon Bovee (b) (4) (b) (4)	07 Apr 2021 18:17:44
User entered '1' reason for change: Data Entry Error	Gordon Bovee (b) (4) (b) (4)	07 Apr 2021 18:17:44
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered 'Yes (Y)'	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered 'Amendment 6 or later (Amendment 6 or later)'	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered '03 Feb 2021'	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered 'Placebo (Placebo)'	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered 'Placebo (Placebo)'	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered 'Placebo (Placebo)'	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User entered 'No (N)'	He (Helen) Pu (b) (4) (b) (4)	29 Mar 2021 21:12:14

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	29 Mar 2021 21:12:14

FDA-CBER-2022-1614-3086467

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:30:49
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered empty.	System	29 Mar 2021 21:12:14

FDA-CBER-2022-1614-3086468

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered 'No (N)'	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:52

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:52

FDA-CBER-2022-1614-3086470

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:52

FDA-CBER-2022-1614-3086471

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:30:49
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered empty.	System	20 Apr 2021 21:27:52

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:30:49
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered 'No (N)'	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:57

FDA-CBER-2022-1614-3086473

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:30:49
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:57

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:30:49
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:20:03
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	20 Apr 2021 21:27:57

FDA-CBER-2022-1614-3086475

US3732110
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:30:49
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered empty.	System	20 Apr 2021 21:27:57

US3732110
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:30:49
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:47:39
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 23:23:33

FDA-CBER-2022-1614-3086477

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:02:37
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:17:01
User entered 'USA-US102-2020-mRNA-1273-P301000003'	System	19 Oct 2020 12:16:56
User entered 'New'	(b) (4), (b) (6)	19 Oct 2020 12:16:56

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:02:39
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as SOC: Product issues, HLGT: Device issues, HLT: Device issues NEC, PT: Lead dislodgement, LLT: Displaced lead cardiac pacemaker - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Oct 2020 20:18:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Oct 2020 20:18:24
Data point term sent to Coder	System	16 Oct 2020 23:31:36
User entered 'Displaced Automated Implantable Cardioverter Defibrillator Lead'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:07:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:07:59
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086481

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:03
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:05
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '08 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086483

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:08
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered empty.	System	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086485

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:10
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 00:25:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Oct 2020 00:25:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 00:25:13
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 23:30:49
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '08 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086487

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:14
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086488

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered empty.	System	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:44
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:46
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	17 Oct 2020 00:25:31
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Oct 2020 23:30:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:49
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086492

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:51
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	17 Oct 2020 00:25:31
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	17 Oct 2020 00:25:31
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 00:25:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	16 Oct 2020 23:30:49
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:08:55
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '08 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086495

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:09:03
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
User entered '09 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086496

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:09:12
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:09:20
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086498

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:09:36
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:09:37
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:09:39
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:10:03
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:10:08
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086503

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:10:11
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'PV Query: Since the subject will not receive any more doses of study drug as both doses have already been provided, the correct action for study drug would be not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:40:05
Query 'PV Query: Since the subject will not receive any more doses of study drug as both doses have already been provided, the correct action for study drug would be not applicable.' answered with 'updated' (Site from Safety).	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:08:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:08:45
User opened query 'PV Query: Since the subject will not receive any more doses of study drug as both doses have already been provided, the correct action for study drug would be not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:38:34
User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:12:43
Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'correct per eCRF guidelines. Not applicable only applies if prior to first dose' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 03:21:29
User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 14:12:51
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:10:36
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded therapeutic procedure that match this AE. Please review and update Other Action Taken as appropriate. Otherwise,clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:42:57
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded therapeutic procedure that match this AE. Please review and update Other Action Taken as appropriate. Otherwise,clarify.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 01:01:21
User entered '0' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 01:00:59
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded therapeutic procedure that match this AE. Please review and update Other Action Taken as appropriate. Otherwise,clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:26:07
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

FDA-CBER-2022-1614-3086505

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:10:38
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:10:41
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '1' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 01:00:59
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:10:43
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:10:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:12:16
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 16:58:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' answered with 'Per source, medical records were requested in October 2020, but were never received. There is no additional information available as subject has now discontinued from study.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 20:10:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:39:14
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:40:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' answered with 'medical records have been requested ' (Site from Safety).	Lauren Arnett (b) (4) (b) (4)	24 Nov 2020 20:09:55
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 20:38:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 20:12:59

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' answered with 'waiting on medical records' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 03:21:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none available, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 14:11:57
User entered 'During day 57 subject reported Implantable Device Replacement and during this procedure it was noted subject had a Displaced AICD Lead which resulted in one overnight stay for observation'	(b) (4), (b) (6)	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:30:49
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '0'	System	16 Oct 2020 23:30:49

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:06:52
Data point term sent to Coder	System	16 Nov 2020 20:48:48
User entered 'post surgical pain bilateral shoulders related to displace automated implantable cardioverter defibrillator lead procedure'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086518

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086520

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
User entered empty.	System	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086523

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '29 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086524

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086525

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
User entered empty.	System	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086531

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086532

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Not Related (NOT RELATED)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Not Related (NOT RELATED)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086540

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'None (NONE)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '1'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

FDA-CBER-2022-1614-3086545

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:13:24
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
User entered '0'	System	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26
User entered '1'	System	16 Nov 2020 20:48:27

US3732110
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:30:49
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:56:26

FDA-CBER-2022-1614-3086550

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 09:30:49
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:21:28
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 17:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 17:41:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 17:41:13
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:41:13

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:45:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:45:22
Data point term sent to Coder	System	21 Aug 2020 17:44:00
User entered 'levothyroxine'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

FDA-CBER-2022-1614-3086552

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'hypothyroidism'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '50'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'ug (ug)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	21 Aug 2020 17:43:40

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:56:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:56:39
Data point term sent to Coder	System	30 Sep 2020 23:26:56
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:26:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:47:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:47:26
Data point term sent to Coder	System	21 Aug 2020 17:46:05
User entered 'allopurinol'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 15:14:25
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'data updated to reflect location' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:26:20
User entered 'GOUT Right big Toe' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:26:07
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:47:02
User entered 'gout'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

FDA-CBER-2022-1614-3086572

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '100'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'un UNK 1990'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:45:48

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	21 Aug 2020 17:45:48

FDA-CBER-2022-1614-3086587

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:47:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:47:10
Data point term sent to Coder	System	21 Aug 2020 17:47:06
User entered 'metropol succinate ER'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'hypertension'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '25'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'un UNK 1995'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:46:26

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	21 Aug 2020 17:46:26

FDA-CBER-2022-1614-3086605

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: THIOCTIC ACID, PRODUCTSYNONYM: ALPHA LIPOIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 03:38:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 03:38:09
Data point term sent to Coder	System	16 Nov 2020 20:51:55
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:51:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: THIOCTIC ACID, PRODUCTSYNONYM: ALPHA LIPOIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:48:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:48:18
Data point term sent to Coder	System	21 Aug 2020 17:47:06
User entered 'alpha lipoic acid'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

FDA-CBER-2022-1614-3086606

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:51:34
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'vitamin deficiency' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:51:34
User entered 'supplement'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '300'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'twice daily (BID)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'un UNK 1990'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '2'	System	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	21 Aug 2020 17:47:03

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE ACETATE, PRODUCTSYNONYM: TAMBOCOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:20:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:20:35
Data point term sent to Coder	System	30 Sep 2020 23:27:57
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:27:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE ACETATE, PRODUCTSYNONYM: TAMBOCOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 12:19:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 12:19:35
Data point term sent to Coder	System	21 Aug 2020 17:49:09
User entered 'flecainide acetate (tambocor)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

FDA-CBER-2022-1614-3086624

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. type of ARRHYTHMIA) to the appropriate Medical History eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 15:14:34
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. type of ARRHYTHMIA) to the appropriate Medical History eCRF. ' answered with 'type of arrythmia updated ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:28:36
User entered 'ARRHYTHMIA ventricular tachycardia' reason for change: Per Query Resolution	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:27:07
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. type of ARRHYTHMIA) to the appropriate Medical History eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:48:26
User entered 'arrhythmia'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

FDA-CBER-2022-1614-3086626

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '100'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'twice daily (BID)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'un UNK 2000'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '2'	System	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	21 Aug 2020 17:48:18

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 07:00:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 07:00:38
Data point term sent to Coder	System	30 Sep 2020 23:29:58
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:29:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 04:47:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 04:47:33
Data point term sent to Coder	System	21 Aug 2020 17:49:10
User entered 'tamulosin (Flomax)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 15:14:38
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' answered with 'data updated to reflect medical history condition ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:30:02
User entered 'benign prostatic hyperplasia' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	30 Sep 2020 23:29:36
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:49:33
User entered 'enlarged prostate'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:38:28
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'data has been corrected ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	20 Nov 2020 21:47:15
User entered '0.4' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	20 Nov 2020 21:46:56
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:21:43
User entered '4'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'un UNK 2015'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	21 Aug 2020 17:48:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
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)	21 Aug 2020 17:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:51:24
Data point term sent to Coder	System	21 Aug 2020 17:50:11
User entered 'aspirin'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'cardiac health'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '81'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'un UNK 1980'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	21 Aug 2020 17:49:30

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 17:51:24
Data point term sent to Coder	System	21 Aug 2020 17:50:11
User entered 'simvastatin'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'hyperlipidemia'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '40'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'un UNK 1980'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	21 Aug 2020 17:50:02

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:08:29
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 Oct 2020 08:08:29
Data point term sent to Coder	System	20 Oct 2020 15:55:44
User entered 'keflex'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

FDA-CBER-2022-1614-3086696

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

FDA-CBER-2022-1614-3086697

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
Query 'Per ETRTR: If medication was dosed for SAE "DISPLACED AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD", please state so within SAE CRF, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:25:37
User opened query 'Per ETRTR: If medication was dosed for SAE "DISPLACED AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD", please state so within SAE CRF, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 21:23:50
User entered 'pacemaker replacement procedure'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '250'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'three times daily (TID)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

FDA-CBER-2022-1614-3086704

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

FDA-CBER-2022-1614-3086706

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

FDA-CBER-2022-1614-3086709

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:54:59

FDA-CBER-2022-1614-3086710

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
User entered '3'	System	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
User entered '1'	System	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:24
User entered '804 (804)'	System	20 Oct 2020 15:54:59

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:58:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 15:58:38
Data point term sent to Coder	System	20 Oct 2020 15:57:47
User entered 'tylenol'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'pacemaker replacement procedure'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '500'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

FDA-CBER-2022-1614-3086718

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'as needed (PRN)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

FDA-CBER-2022-1614-3086722

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

FDA-CBER-2022-1614-3086724

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

FDA-CBER-2022-1614-3086726

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '16 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

FDA-CBER-2022-1614-3086727

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:57:10

FDA-CBER-2022-1614-3086728

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User entered empty.	System	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User entered empty.	System	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User entered empty.	System	20 Oct 2020 15:57:10

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GOUT RIGHT BIG TOE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 08:03:46
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GOUT RIGHT BIG TOE should be recorded, and update con med indication or provide clarification. ' answered with 'added in addition to other medication for gout' (Site from DM).	Gordon Bovee (b) (4) (b) (4)	16 Jan 2021 19:56:05
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GOUT RIGHT BIG TOE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 16:50:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:12:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 02:12:50
Data point term sent to Coder	System	16 Nov 2020 20:50:52
User entered 'colchicine'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

FDA-CBER-2022-1614-3086732

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'gout right big toe'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0.6'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mg (mg)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

FDA-CBER-2022-1614-3086736

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'once daily (QD)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

FDA-CBER-2022-1614-3086738

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

FDA-CBER-2022-1614-3086740

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '01 Nov 2020'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	16 Nov 2020 20:50:41

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '1'	System	16 Nov 2020 20:50:41

FDA-CBER-2022-1614-3086748

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User entered '804 (804)'	System	16 Nov 2020 20:50:41

FDA-CBER-2022-1614-3086749

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
User closed query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:58:39
Query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' answered with 'deviation recorded in source' (Site from DM).	Gordon Bovee (b) (4) (b) (4)	02 Apr 2021 00:26:32
User opened query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 00:15:43
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 01:00:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 01:00:42
Data point term sent to Coder	System	08 Feb 2021 20:22:00
User entered 'covid-19 vaccine'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

FDA-CBER-2022-1614-3086750

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

FDA-CBER-2022-1614-3086751

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'covid-19 vaccine'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0.5'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'mL (mL)'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'once (ONCE)'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Intramuscular (INTRAMUSCULAR)'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '24 Jan 2021'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '0'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '24 Jan 2021'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:28:04
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
User entered empty.	System	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
User entered empty.	System	08 Feb 2021 20:21:57

US3732110
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:30:49
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:28
User entered empty.	System	08 Feb 2021 20:21:57

FDA-CBER-2022-1614-3086767

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:30:49
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:30:02
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:18

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:30:49
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:29:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:41

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:30:49
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:29:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'PACEMAKER REPLACEMENT'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:41

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:29:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Medical History (MH)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:41

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:30:49
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:29:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:50:41

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:30:49
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:37:50
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:29:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '08 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:51:58

FDA-CBER-2022-1614-3086773

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:30:49
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:37:50
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:29:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'automated implantable cardioverter defibrillator lead replacement'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:51:58

FDA-CBER-2022-1614-3086774

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:30:49
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:37:50
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:29:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Medical History (MH)'	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:51:58

US3732110
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:30:49
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:37:50
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 18:29:52
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	20 Oct 2020 15:51:58

US3732110
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:30:49
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:27:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
Signature has been broken.	He (Helen) Pu (b) (4) (b) (4)	24 Mar 2021 16:39:03
User entered '03 Feb 2021' reason for change: Data Entry Error	He (Helen) Pu (b) (4) (b) (4)	24 Mar 2021 16:39:03
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '24 Jan 2021'	He (Helen) Pu (b) (4) (b) (4)	04 Feb 2021 02:20:31

US3732110
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:30:49
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:27:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
User closed query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 18:26:38
Query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' answered with 'UPDATED ' (Site from DM).	He (Helen) Pu (b) (4) (b) (4)	24 Mar 2021 16:39:15
Signature has been broken.	He (Helen) Pu (b) (4) (b) (4)	24 Mar 2021 16:39:03
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	He (Helen) Pu (b) (4) (b) (4)	24 Mar 2021 16:39:03
User opened query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:56:06
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Other (OTHER)'	He (Helen) Pu (b) (4) (b) (4)	04 Feb 2021 02:20:31

US3732110
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:30:49
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 06:27:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 23:01:07
Signature has been broken.	He (Helen) Pu (b) (4) (b) (4)	24 Mar 2021 16:39:03
User entered 'SUBJECT RECEIVED OUTSIDE MODERNA VACCINE (FIRST DOSE) ON 24JAN2021. RELAYED TO SITE 03FEB2021.' reason for change: Data Entry Error	He (Helen) Pu (b) (4) (b) (4)	24 Mar 2021 16:39:03
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered 'Received outside vaccine'	He (Helen) Pu (b) (4) (b) (4)	04 Feb 2021 02:20:31

US3732110
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:30:49
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:27:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	04 Feb 2021 02:20:31

US3732110
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:30:49
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:27:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	04 Feb 2021 02:20:31

US3732110
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:30:49
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:27:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	04 Feb 2021 02:20:31

FDA-CBER-2022-1614-3086782

US3732110
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:30:49
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:27:45
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	04 Feb 2021 02:20:31

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

FDA-CBER-2022-1614-3086794

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

FDA-CBER-2022-1614-3086798

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '3'	System	25 Nov 2020 17:40:32
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

FDA-CBER-2022-1614-3086811

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '3'	System	25 Nov 2020 17:40:32
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:30:49
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '19/Oct/2020 12:19'	System	19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:30:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered '1'		19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

FDA-CBER-2022-1614-3086828

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

FDA-CBER-2022-1614-3086831

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

FDA-CBER-2022-1614-3086832

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '3'	System	25 Nov 2020 17:40:32
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 09:30:49
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '10/Nov/2020 14:55'	System	10 Nov 2020 19:55:15

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 09:30:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:40:20
User entered '1'		10 Nov 2020 19:55:15

FDA-CBER-2022-1614-3086835

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

FDA-CBER-2022-1614-3086844

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

FDA-CBER-2022-1614-3086846

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '3'	System	25 Nov 2020 17:40:32
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:30:49
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09

FDA-CBER-2022-1614-3086852

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:30:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 17:40:20
User entered '0'		10 Nov 2020 19:55:15

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'USA-US102-2020-MRNA-1273-P301000003'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Yes (Y)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'No (N)'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Scott'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'Overcash'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '5565 Grossmont Center Dr'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'La Mesa'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered 'CA'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 12:19:38
User entered '91942'	System	19 Oct 2020 12:16:56

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:54:52
User entered 'US'	System	19 Oct 2020 12:19:44

FDA-CBER-2022-1614-3086868

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:30:49
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '3'	System	25 Nov 2020 17:40:32
User entered '2'	System	10 Nov 2020 19:55:15
User entered '1'	System	19 Oct 2020 12:19:44

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:30:49
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	24 Feb 2021 23:25:23
User entered '25/Nov/2020 17:40'	System	25 Nov 2020 17:40:32

US3732110
Folder: SAE USA-US102-2020-MRNA-1273-P301000003
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:30:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:37:09
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:45:18
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 23:25:23
User entered '1'	(b) (4), (b) (6)	25 Nov 2020 17:40:32

FDA-CBER-2022-1614-3086871